UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of	)	
	)	
Sporicidin International,	)	Docket No. FIFRA-88-H-02
	)	
Respondent	)	

Federal Insecticide, Fungicide and Rodenticide Act - Inspections - Search Warrants - Federal Standards

Search conducted at the instance of EPA by employees of the District of Columbia Government, who carried inspector's credentials issued by the D.C. Government and EPA, under a warrant issued by the Superior Court of the District, was a federal search and federal standards were applicable. Because evidence that pesticides were held for distribution or sale at the premises searched was stale and outdated, the search could not be justified under § 9 of FIFRA and evidence seized during the search was suppressed.

Federal Insecticidie, Fungicide and Rodenticide Act - Section 12(a)(1)B - Claims - Distribution or Sale

Where evidence established that Respondent delivered promotional material to D.C. General Hospital, which made statements as to the effectiveness of its products as disinfectants against the AIDS virus, at the same time the pesticide products were present or being used there, and the mentioned statements were not included in statements as to the pesticides' effectiveness accepted as part of the products' registration, the statements were held to be claims within the meaning of § 12(a)(1)(B) and, under the circumstances, and absent evidence to the contrary, it

would be presumed that the claims were made to induce purchase and use of the products and, thus, a part of their distribution or sale.

Federal Insecticide, Fungicide and Rodenticide Act - Labeling - Collateral Advertising - Misbranding

Although § 2(p)(2) of the Act defines "labeling" as including all labels and all other written, printed or graphic matter accompanying the pesticide or device at any time, the mere fact that Respondent delivered a pesticide product to D.C. General Hospital, at a time collateral advertising materials making claims for the product were present at the Hospital, did not establish that the advertising materials accompanied the product so as to constitute labeling and count of complaint charging misbranding was dismissed.

Federal Insecticide, Fungicide and Rodenticide Act - Rules of Practice - Penalties - Burden of Proof

Although there was no evidence in the record of Respondent's sales, revenues or financial condition and § 14(a)(4) of Act directs Administrator to consider, inter alia, size of Respondent's business and effect on its ability to continue in business in determining amount of penalty, assessment of maximum penalty for each offense was held to be proper, because Respondent had raised no issue as to its size or financial condition in contesting imposition of penalty and Rules of Practice placed burden of raising such issues on Respondent.

Appearance for Respondent:
Mr. T. J. Schattner
Vice President
Sporicidin International
Rockville, MD

Appearance for Complainant:
Frederick F. Stiehl, Esq.
Marged G. Harris, Esq.
Toxics Litigation Division
Office of Enforcement and
Compliance Monitoring
U.S. EPA
Washington, D.C.

INITIAL DECISION

This is a proceeding under § 14(a) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (7 U.S.C. § 136 1(a)). The proceeding was commenced on October 13, 1987, by the issuance of a complaint by the Director Compliance Division, U.S. EPA Headquarters, charging Respondent, Sporicidin International, with violating § 12(a)(1)(B) of the Act in that Respondent made claims for the effectiveness of its pesticide product, Sporicidin Cold Sterilizing Solution (Sporicidin), against the Hepatitis B and HTLV III/LAV (AIDS) viruses which differed from those accepted in connection with the product's registration. For this alleged violation of the Act, it was proposed to assess Respondent a penalty of $5,000.

Respondent answered, denying the conduct which resulted in the violation alleged, requesting dismissal of the complaint and demanding the return of all materials seized from its offices on August 21, 1987. On December 17, 1987, Respondent filed a motion for an accelerated decision dismissing the complaint for the reason that it failed to state a cause of action and moving for suppression of evidence seized during an inspection on August 21, 1987, alleging the search was illegal. In an order, dated February 22, 1988, the motion to suppress was denied, because the search, conducted under a warrant issued by the Superior Court of the District of Columbia, was justified under D.C. law and regulation, even though it could not be justified under FIFRA.

The motion to dismiss was, however, conditionally granted unless Complainant moved within 20 days to amend the complaint to allege that the claims for Sporicidin's effectiveness were made as part of its distribution or sale.

On March 8, 1988, Complainant filed a motion to amend the complaint. This motion was granted on March 22, 1988, over Respondent's objection.1/ The amended complaint contained three counts: Count I alleged that Respondent made claims for the effectiveness of Sporicidin Cold Sterilizing Solution, a pesticide, against the Hepatitis B and HTLV III/LAV (AIDS) viruses, in connection with the product's distribution or sale which substantially differed from claims accepted in connection with its registration in violation of § 12(a)(1)(B) of the Act; Count II alleged that Respondent made claims for the effectiveness of Sporicidin Brand Disinfectant Spray (Permacide) against the HTLV III/LAV (AIDS) virus in connection with the product's distribution or sale which differed substantially from claims accepted in connection with its registration in violation of § 12(a)(1)(B) of the Act and Count III alleged that Respondent had made shipments of Sporicidin Cold Sterilizing Solution (Sporicidin) to D.C. General Hospital on June 5, July 31 and September 21, 1987, which were misbranded

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1/ Respondent had moved under date of February 26, 1988, for an order reversing or modifying the order denying its motion to suppress and modifying the order conditionally granting the motion for an accelerated decision. Respondent further objected to the amended complaint in a motion to quash, filed March 17, 1988, and in an Exception to Court's Holding, filed April 21, 1988.

in violation of § 12(a)(1)(E) of the Act, in that labeling accompanying the product made claims for the effectiveness of the product against the AIDS virus which were and are false and misleading. For these alleged violations it was proposed to assess Respondent a penalty totaling $15,000. Respondent answered, denying the alleged violations, renewing its motion for dismissal in a purported "cross-complaint" and filing a new motion for an accelerated decision. These motions were denied by an order, dated April 19, 1988, to which Respondent excepted (note 1, supra).

A hearing on this matter was held in Washington, D.C., on May 23, 1988.

Based on the entire record including the proposed findings and briefs submitted by the parties, I make the following:

FINDINGS OF FACT

1. Respondent, Sporicidin International, also known as The Sporicidin Company, or R. Schattner Company, after its president, is a person as defined in § 2(s) of FIFRA. Respondent is a corporation organized under District of Columbia law.
2. Respondent holds registrations for and is the manufacturer of Sporicidin Cold Sterilizing Solution (EPA Registration No. 8383-5) (Sporicidin) and Sporicidin Brand Disinfectant Spray (EPA Registration No. 8383-4) (Permacide). Registration of the former product was granted on February 20, 1980, and

amended registrations or labels were approved on March 20, August 26, and September 24, 1987 (Exhs 7, 11, 12 and 15).2/ Registration of Permacide was granted on October 25, 1972 (Exh 70) and revised labeling was approved on April 19, 1988 (Exh 71). These products are pesticides as defined in § 2(u) of the Act.

3. Respondent's advertisements for Sporicidin contained statements that "(a) Sporicidin, diluted 1:16 inactivates the Hepatitis B virus in 10 minutes (Centers for Disease Control [CDC], Phoenix, Arizona)," "In controlled studies Sporicidin (1:16) inactivated the AIDS, Hepatitis B and Herpes Viruses in 10 minutes" (Attachments to EPA letter to Respondent, dated June 30, 1986, Exh 1). Respondent's advertising as aforesaid led to trade complaints or inquiries as to whether the claims for Sporicidin varied from those accepted in connection with the product's registration or were false and misleading (testimony of Sandra Spencer, an EPA Environmental Specialist, Tr. 143; Record of Communication, dated February 13, 1986, Exh 19).

4. Respondent was one of 13 registrants targeted for investigation for false or misleading claims in advertising disinfectants (testimony of Michael Hackett, an EPA Environmental Specialist,

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2/ Because Complainant's exhibits far outnumber those of Respondent, references to exhibits will be to those of Complainant, unless otherwise indicated.

Tr. 32, 33; letter from Assistant Administrator John A. Moore to Robert I. Schattner, dated October 27, 1987, Respondent's Exh 3; Disinfectant Claims Update 4-21-88, Exh 77). On June 24, 1987, a request for an investigation of Respondent concerning false or misleading claims as to the effectiveness of Sporicidin was forwarded to EPA Region III, Philadelphia, Pennsylvania (Tr. 33, 34; Exh 23). Attached to the request were copies of letters, dated June 30 and September 12, 1986, issued to Respondent by the Compliance Monitoring Division and the Registration Division, EPA Headquarters, informing Respondent that claims made in collateral literature for the effectiveness of Sporicidin against the Hepatitis B and HTLV III/LAV (AIDS) viruses were unacceptable. Collateral literature referred to included a copy of a page from the American Dental Association News, dated December 16, 1985, which contains an advertisement stating "(i)n controlled studies . . . Sporicidin (1:16) inactivated the AIDS virus in 10 minutes" and an advertisement from the January 1986 issue of Dental Economics which states in part "(i)n controlled studies Sporicidin (1:16) inactivated the AIDS, Hepatitis B and Herpes viruses in 10 minutes."3/ The Investigation Request

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3/ In a letter, dated July 10, 1986 (Exh 2), Respondent stated it had ceased using the ad in Dental Economics as well as comparable promotional sheets prior to receipt of the EPA letter, dated June 30, 1986. Respondent also stated that it had ceased using certain statements which appeared in the December 16, 1985, issue of ADA News. Regarding references to a CDC study involving the use of germacides against Hepatitis B, Respondent pointed out that EPA had previously accepted such references (note 15, infra).

was sent to Philadelphia, because at the time Respondent's headquarters were in the District of Columbia and the District is in EPA Region III. In accordance with § 26 of the Act, the D.C. Government (Department of Consumer and Regulatory Affairs) (DCRA) has primary enforcement responsibility for FIFRA in the District (Tr. 32).

5. On July 21, 1987, the request for an investigation referred to in the preceding finding was received by the DCRA (testimony of Mark Greenleaf, Environmental Specialist, DCRA, Tr. 79, 81; memorandum, Exh 39). On August 18, 1987, Mr. Greenleaf accompanied by Mr. John Davidson, another Environmental Specialist in the DCRA, attempted an inspection of Respondent's offices at 4000 Massachusetts Ave., N.W., Washington, D.C. (Tr. 81, 82; Notice of Inspection, Exh 33). Mr. Greenleaf carries official inspector's credentials from EPA as well as from the D.C. Government (Tr. 98). He testified that the District receives money from EPA to run the [pesticide] program and that he could be regarded as an employee [of EPA]. The Notice of Inspection recited that the reason for the inspection was, inter alia, "(f)or the purpose of inspecting and obtaining samples of any pesticides or devices packaged, labeled, amd (sic) released for shipment, and samples of any containers or labeling for such pesticides or devices, in places where pesticides or devices are held for distribution or sale. (Sec. 13(a) of DCPOA and 12(a)(2)(B) of FIFRA)."

The violation suspected was "False or Misleading claims. Formal referral from E.P.A. headquarters via E.P.A. Region 3 office to State Lead Agency in District of Columbia to investigate any false or misleading claims in product labeling, advertising, literature, or any other correspondence referencing the product 'Sporicidin Cold Sterilizing Solution' EPA Registration Number 8383-5." Messrs. Greenleaf and Davidson were met by Mr. Ted Schattner, Respondent's Vice President, who declined to permit the inspection (Tr. 82; Narrative Report, Exh 34).

6. On August 20, 1987, Diana Haines, Acting Chief of the DCRA, executed an Application For An Administrative Search Warrant in the Superior Court Of The District Of Columbia (Exh 35). The application recited the referenced request for an investigation of Respondent from EPA Region III, advertisements for Sporicidin in the American Dental News and Dental Economics referred to above (finding 4) and the refusal of Mr. Ted Schattner to permit the inspection. The application further recited that 20 DCMR 1007.6 makes it unlawful for any person to make false or fraudulent claims through any media that misrepresents the effect of a pesticide and identified the Respondent as "Robert I. Schattner, DDS, President t/a R. Schattner Company, a/k/a Sporicidin International." On August 20, 1987, Mr. Greenleaf executed an Affidavit In Support Of An Application For A Search Warrant (Exh 38). The affidavit essentially repeated the facts referred to above

from the application and concluded there is probable cause to believe that Sporicidin International is disseminating false and/or misleading advertisements in contravention of Title 20, DCMR. Acting on the mentioned application and affidavit, Judge Rufus King of the D.C. Superior Court issued an Order on August 20, 1987, for An Administrative Search Warrant To Robert I. Schattner, D.D.S. t/a Sporicidin International, 4000 Massachusetts Avenue, N.W., Suite 828 for the purpose of investigating violations of 20 DCMR, Chapter 10-13 (Exh 40) and a Warrant For Inspection Under The District Of Columbia Municipal Regulation. The warrant was directed to the Chief of Police or any authorized Police Officer of the Metropolitan Police Department and responsible agents of the DCRA and authorized entry of the described premises of Respondent during ordinary business hours for the purpose of "determining compliance with Title 20, DCMR, Chapters 10 through 13 by sampling, photographing and obtaining evidence concerning false or misleading claims with respect to the product Sporicidin Cold Sterilizing Solution (EPA Reg. No. 8383-5)" (Exh 41).

7. The warrant was executed on August 21, 1987, by two, initially three, police officers from the Metropolitan Police Department and representatives from the DCRA including Mark Greenleaf and John Davidson (Tr. 84, 106-107; Return, Exh 42; memorandum, Exh 39). A Notice Of Inspection differing only slightly from the Notice issued at the time of the attempted inspection on August 18, 1987, was issued to Mr. Ed Faeth, manager of

administrative services for Respondent (Exh 43). The inspection was conducted by Messrs. Greenleaf and Davidson. Samples of advertising literature and promotional material were collected from a display area and marked with Mr. Greenleaf's initials and the date and identified as Exhibits A & B (Tr. 116; Receipt For Samples, Exh 44). In addition, two cardboard posters were collected, one reading "AIDS In controlled studies, Sporicidin (1:16) inactivated the AIDS virus in 10 minutes," while the second reads "Hepatitis Sporicidin effective against Hepatitis B virus in 10 minutes (Centers for Disease Control, Phoenix, Arizona)."4/ Photos were taken of the display area and of posters and informational materials on the walls (Receipt For Samples, Exh 46; photos, Exh 50). Although Mr. Greenleaf acknowledged opening file drawers labeled "users,"5/ he denied opening any desk drawers (Tr. 117). His memorandum, however, casts some doubt on this testimony, stating in part: "Messrs. Greenleaf and Davidson did not search any files or desks that were not labeled referencing advertising literature, distributors or users" (Exh 39).

4/ Tr. 87; Receipt For Samples, Exh 45; Collection Report, Exh 47. While similar language appears on other literature collected during the inspection, it is not clear that these posters are included in literature in the record (Exh 48). It is noted that the Enforcement Case Review (Exh 75) states posters were not provided. The initial page of literature collected at D.C. General Hospital (Exh 28) appears, however, to meet the description of the first of the mentioned posters.

5/ This apparently resulted in the collection of a document entitled "Sporicidin - HD: Partial List of Users" "Exh A" (Exh 49).

8. Literature seized at the time of the inspection of Respondent's offices on August 21, 1987, included claims for the effectiveness of Sporicidin similar or indentical to those referred to in findings 4 and 7. For example, the literature contained statements such as "Proven - The most effective cold sterilant and disinfectant ever registered by the E.P.A.," "A C.D.C. study indicates that a 1:16 dilution of Sporicidin is effective against the hepatitis B virus in 10 minutes,"6/ "Sporicidin 1:16 killed AIDS (HTLV III) virus after a 10 minute incubation at 20°C" and "Sporicidin 1:16 kills the Herpes I and II viruses in 10 minutes" (Exh 48). Included in materials seized were Abstracts of the Annual Meeting of the American Society for Microbiology (1982), which contained a summary report "Effects of Chemical Germicides on Hepatitis B Virus Infectivity" by the Centers of Disease Control, Phoenix, Arizona. The tests involved inoculating a chimpanzee with a human plasma inoculum known to contain infectious doses of Hepatitis B after the plasma was exposed to a germacide at 20°C for ten minutes. One of five germacides tested was Sporicidin. After post inoculation times of up to five months, none of the chimpanzees reportedly showed any evidence of infection. The study concluded that if the results are the same after nine months, it would indicate that medium

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6/ Exh 19. In its letter, dated July 10, 1986 (note 3, supra), Respondent specifically stated it had ceased making these claims.

to high level disinfectants can be used to inactivate HBV.7/ An article entitled "Precautions to Prevent the Spread of Hepatitis in the Dental Office" from Clinical Preventive Dentistry was also seized during the inspection. An abstract of this article states in part "(s)ince tissue fluids, such as blood and saliva, can harbor the Hepatitis B virus, instruments used and surfaces normally touched by the dentist or assistant should be cleaned and disinfected with Sporicidin cold sterilizing solution, which was found effective against the Hepatitis B virus by the Centers for Disease Control (CDC)." This article was authored by a Ms. Ree Wilkinson, who is identified as Clinical Supervisor, Providence Hospital Dental Clinic, Washington, D.C.

9. As found above (finding 6), the warrant issued by the D.C. Superior Court was limited to obtaining evidence of false or misleading claims concerning Sporicidin. Documents seized, however, included p. 25 of the June/July issue of Modern Dental Lab which includes a picture of a container "Sporicidin Disinfectant Spray," which is identified as a companion product to the company's cold sterilizing solution. Printed material beneath the photo states "Sporicidin Disinfectant Spray was found to be tuberculocidal, bactericidal, fungicidal and virucidal--including AIDS (HTLV III), herpes I and II,

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7/ Copies of the report of the results of this study "Inactivation of Hepatitis B Virus by Intermediate-to-High-Level Disinfectant Chemicals," which indicates there was no evidence of infection after post-inoculation periods of nine months, are in the record (Respondent's Exh 11, Exh 19).

influenza A_2 and polio I and II. It is available in a 22-oz. aerosol can." Another document seized relating to Sporicidin Brand Disinfectant Spray, trade name Permacide, is what purports to be a report, dated January 23, 1986, on a study of the effectiveness of Permacide against the HTLV III (Virus). The report is on the letterhead of Bionetics Research, is addressed to Dr. Curtis L. Lynch of Respondent and states in pertinent part: "(i)n conclusion, the study demonstrates that undiluted sporicidin brand disinfectant spray (permacide) is effective in killing HTL-III (AIDS) virus in 1, 5 or 10 minutes at 20°C (Part A)." Mr. Greenleaf acknowledged that he did not find any evidence during the inspection that Respondent's offices were used to hold Sporicidin for distribution or sale (Tr. 120).

10. Mr. Greenleaf conducted an inspection at D.C. General Hospital on October 13, 1987 (Tr. 88, 92; Notices of Inspection, Exhs 25 and 61). Mr. Greenleaf took a statement from Ms. Janice Harris, identified as a secretary working in the Diagnostic Center at D.C. General (Tr. 89, 90, 181; Exh 27). The statement is to the effect that Ms. Harris received a packet of literature, from whom not stated, which included claims

referencing Sporicidin Cold Sterilizing Solution's effectiveness against the AIDS virus on or about June 18, 1987, in the auditorium at D.C. General Hospital. The package of literature (Exh 28)[8/] appears to include a poster or a copy thereof similar to one collected by Mr. Greenleaf at the time of the inspection of Respondent's offices on August 21, 1987 (note 4, supra). The literature includes an "Info-Gram," dated December 13, 1985, which under a heading "Important Research Findings" states in part "In controlled studies, Sporicidin (1:16) inactivated the AIDS (HTLV III) virus in 10 minutes at room temperature,"[9/] other literature similar or identical to that described previously (findings 3, 4 & 8), and research reports or summaries thereof purportedly concerning Sporicidin's effectiveness as a disinfectant, as well as product data, a document labeled "Sporicidin Cold Sterilizing Solution Questions And Answers" and directions for use of Sporicidin.

11. Mr. Greenleaf took a statement from Dr. Joan Postow, a medical doctor working in the Diagnostic Center at D.C. General, at the time of his inspection on October 13, 1987 (Tr. 90, 91;

8/ Although Ms. Spencer, identified finding 3, testified that Exhibit 28 consisted of advertising and promotional material collected by Mr. Greenleaf at the time of his inspection of Respondent's offices in August 1987 (Tr. 137), Mr. Greenleaf identified the mentioned exhibit as material received from Ms. Harris at the time of his first inspection of D.C. General Hospital on October 13, 1987. He identified materials collected during his inspection of Respondent's offices with his initials and the date (finding 7) and it is concluded Ms. Spencer's testimony in this regard is erroneous.

9/ This "Info-Gram" or a copy thereof appears in one of the photos taken by Mr. Greenleaf at the time of the August 21 inspection of Respondent's offices (Exh 50).

Exh 29). Dr. Postow states that on or about June 17, 1987, she received literature from office staff concerning AIDS claims for Sporicidin cold sterilizing solution and that the literature would have been received by office staff within two weeks prior to June 17, 1987. By letter, dated June 17, 1987 (Exh 26), Dr. Postow sent the Bionetics' studies (findings 9 and 12) to Mr. William Campbell, Chief Technical Support Section, Disinfectants Branch at EPA (Tr. 73; Exh 26).

12. A statement from Ms. Carlotta Teal, a health technician at D.C. General, says that on or about May 15, 1987, she received directly from Dr. Curtis Lynch, representing Sporicidin International, literature containing claims regarding the effectiveness of Sporicidin cold sterilizing solution against the AIDS virus (Tr. 175-76; Exh 30). As a health technician in the diagnostic suite, Ms. Teal's responsibilities include the maintenance and disinfection or sterilization of equipment (Tr. 173). For this purpose, Sporicidin is used as a cold sterilant. Literature referred to includes a report on a Sporicidin 1:16 (AIDS) HTLV III Study, dated January 9, 1986, on the letterhead of Bionetics Research addressed to Dr. Curtis L. Lynch of Respondent. The report states "* * the study demonstrates that Sporicidin at 1:16 dilution is effective in killing HTLV-III (AIDS) virus in 10 munutes at 20°C (Part A)." Also included in the literature was a similar report on the letterhead of Bionetics Research, dated January 23, 1986, concerning Permacide referred to previously

(finding 9) and directions for use of Sporicidin. Ms. Teal gave the literature to Dr. Postow (Tr. 176). She testified that she received the materials directly from Dr. Lynch on two occasions and that a seminar given by Dr. Lynch, which she attended, was in the early part of 1987. Ms. Teal acknowledged that Sporicidin was used at the Hospital not because of its claimed effectiveness against the AIDS and Hepatitis B viruses, but because CDC recommended use of a high level disinfectant (Tr. 180).

13. Mr. Greenleaf conducted a follow-up inspection at D.C. General Hospital on February 29, 1988 (Tr. 92; Notice Of Inspection, Exh 61). He took a statement from Ms. Mae Cundiff, CIC, and Cheryl S. Wilson, RN, who staff the Infection Control Unit at the Hospital. The statement is to the effect that Ms. Cundiff received a package of literature containing 25 pages from Sporicidin International representatives within the past 12 months (Exh 62). Handwritten notes in the literature are those of Ms. Wilson.10/ The literature (Exh 69) includes copies of the Bionetics Research studies on Sporicidin and Permacide referred to previously (findings 9 & 12); a hospital price schedule for Sporicidin; a comparison "Hospital Level Disinfection Sporicidin vs. Cidex Type Products," an advertisement for Sporicidin Brand Disinfectant Spray which states, inter alia, that the product is tuberculocidal, virucidal, fungicidal and

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10/ These notes do not appear to be included in the copies of literature in the record.

bactericidal; an article or abstract thereof from the March 1983 issue of the Journal of Dental Research "Evaluation Of Sporicidin and Cidex Following Clinical In-Use Conditions" by the U.S. Army Institute of Dental Research, Washington, D.C.; a Laboratory Report issued by Gibraltar Biological Laboratories, Inc., assay date 1/28/83, which concludes that "(a)ctivated Sporicidin Cold Sterilizing Solution, aged 21 days then diluted 1:35 (with 35 parts water), completely inactivated the Genital Herpes virus in 10 minutes in the presence of organic soil;" and a report on the letterhead of Milligan College, Milligan College, Tennessee, dated March 9, 1984, by Dr. Eddie Leach, Ph.D.11/ to Dr. Robert Schattner, President of Respondent, which concludes that "Sporicidin diluted 1:16 (with 15 parts of tap water) is hypo-allergenic when tested according to the 'sensitization technique in man' test method."

14. Also included in the literature was an article "An Efficacy Evaluation of a Synergized Gluteraldehyde-Phenate Solution in Disinfecting Therapy Equipment Contaminated During Patient Use" by Timothy R. Townsend, M.D., and others of the John

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11/ An affidavit by a Mrs. Eddie D. Leach, also identified as Margarie Leach, further identified as an administrative assistant of Sporicidin International, Jonesborough, Tennessee, taken at the time of an inspection of Respondent's Jonesborough Tennessee plant on July 1, 1986, is to the effect that during January and February 1986, Respondent sent us copies of the Bionetics Research study on Sporicidin's effectiveness against the AIDS HTLV virus with instructions that the studies were to be provided to customers on request (Exh 21). The affidavit points out that these claims are not part of the labeling for Sporicidin, EPA Reg. No. 8383-5.

Hopkins University School of Medicine, reprinted from Infection Control (1982); a commentary on this article by Dr. Curtis L. Lynch, Respondent's medical director, which extolls the alleged superiority of Sporicidin as a disinfectant; a similar article on the evaluation of a gluteraldehyde-phenate solution to disinfect endoscopes and instruments in a freestanding surgical facility (1983) by Marian Kennedy, RN, Director of Nursing, Center for Ambulatory Surgery, Inc., Washington, D.C.; a similar article by Beth Derby, RN and Evyleen McGucken, RN, from Orthopaedic nursing (1984) on the use of Sporicidin to disinfect arthroscopes; an "Info-Gram" from Respondent addressed to D.C. General Hospital, which states, inter alia, that EPA has approved the following claims for Sporicidin: Diluted 1:16, Is Tuberculocidal And Can Be Used and Re-Used For 30 days For 100% Hospital Level Disinfection In 10 Minutes At True Room Temperature 68°F (And Above);" and a copy of the previously described study by the CDC involving the effectiveness of germacides against the Hepatitis B Virus where chimpanzees were used as test subjects (finding 8).

15. At the time of his second inspection of D.C. General Hospital, Mr. Greenleaf served a Notice of Inspection on Augustus Woods, Manager of Stores and Purchasing (Tr. 93; Exh 63). Mr. Greenleaf proceeded to take photos of bottles of Sporicidin, of the boxes containing the bottles and of a shipping carton or

cartons which indicate the carton contains six boxes, each box containing four 8-oz. bottles for a total of 24 8-oz. units (Tr. 94; Receipt For Samples Exh 64; Photos, Exh 76). Statements on the bottles of Sporicidin include: ".Sporicidal . Virucidal . Tuberculocidal . Bactericidal . Fungicidal . Pseudomonacidal." Also included on the bottles and boxes beneath "Sporicidin Cold Sterilizing Solution" in large letters was the following: "Sporicidin diluted 1:16 can be used and reused for 30 days for 100% hospital level disinfection in 10 minutes against bacteria, pathogenic fungi, tubercle bacillus and viruses at full range of room temperatures 20°C/68°F (and above) in manual systems (bucket or tray)." In addition the boxes of Sporicidin contained the following: "An Economical Disinfectant A Unique Gluteraldehyde-Phenate Complex that is diluted 1:16 for 10-minute disinfection. Does not yellow hands. Safe for Scopes. Saves storage space. Substantial savings in operating costs Complete Hospital Level Disinfection."

16. The carton or cartons of Sporicidin had been shipped from Respondent's plant in Jonesborough, Tennessee via United Parcel Service (Collection Report, Exh 65). Receiving and Acceptance Reports collected by Mr. Greenleaf indicate that orders for Sporicidin were placed by the Hospital on May 21, July 20 and September 14, 1987, and received on June 15, July 31 and September 21, 1987, respectively (Tr. 95, 96; Exhs 68, 66 and 67). In response to a question as to whether he found any

indication or evidence that the literature accompanied the product, Mr. Greenleaf replied that he was not sure he could make that kind of conclusion stating "(w)e found the product at the hospital. We found literature at the hospital" (Tr. 126-27). Mr. Greenleaf's equivocation notwithstanding, it is concluded that the foregoing constituted a negative answer.

17. Ms. Cheryl Wilson, identified finding 13, testified that among the functions of the Infection Control Unit was the monitoring of infections and the approval of products used at the Hospital (Tr. 158-59). She stated that Sporicidin was used as a disinfectant at the Hospital and had been so used for approximately three years. She confirmed Ms. Teal's testimony (finding 12) that Sporicidin was used, not because of any claims that it was effective against the AIDS or Hepatitis viruses, but because CDC recommended use of high-level disinfectants (Tr. 171). She further stated that Dr. Curtis Lynch had made them aware of Sporicidin, had brought Sporicidin to the Hospital and that she had discussed Sporicidin with Dr. Lynch on several occasions (Tr. 160-62). Within the past year, Dr. Lynch had also introduced Hospital personnel to Permacide, the spray disinfectant.12/ Dr. Lynch delivered

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12/ Although a bottle of Permacide, which Ms. Wilson testified had been brought to her office by Dr. Lynch and had been on her file cabinet (Tr. 161) was produced at the hearing, testimony as to use of product at the Hospital related to Sporicidin cold sterilant rather than Permacide. Ms. Teal, however, stated Permacide was in the Diagnostic Center at the Hospital (Tr. 182). Other than this testimony and the can produced at the hearing, there is no evidence of Respondent's distribution of, or the Hospital's purchase of, Permacide.

in person and mailed to the Hospital instructional and promotional material on Sporicidin. Ms. Wilson recalled one meeting in her office where Dr. Lynch told them Sporicidin, the cold sterilant, would kill HIV (AIDS) and HVSA G viruses. Within the past year, she had attended a seminar given by Dr. Lynch and others (Tr. 172). To her recollection, the subject of AIDS was not discussed.

18. Ms. Juanita Wills, Chief of the Disinfectants Branch in EPA's Office of Pesticide Programs, explained the distinction in EPA's view between a sterilizer and a disinfectant. She stated a sterilizer is an antimicrobial agent[13/] that destroys all viruses, bacteria and fungi--in short, it denotes killing all microorganisms against which the product had been tested, while a disinfectant was a more limited type of product, being effective only against specific viruses against which the product had been tested (Tr. 39, 40). See 40 CFR § 162.3(ff)(2)(i). Sterilants involve a long time immersion process of from 6 3/4 hours to 10 hours, whereas disinfectants kill in 10 minutes.[14/] Ms. Wills explained that for the latter purpose, EPA only permitted [disinfection] claims if tested against a specific virus (Tr. 40). She

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13/ Antimicrobial agents are products which inhibit the growth of or destroy bacteria, fungi or viruses within an inanimate environment (Tr. 38). It includes products such as disinfectants, sterilizers, sanitizers, commodity preservatives, fungicides and fungistats.

14/ In addition to the time factor,, sterilization processes may damage equipment (Tr. 175). Accordingly, the importance of acceptable disinfectants for medical instrument and equipment applications is obvious.

asserted that EPA had not approved any disinfectant product for control of AIDS or hepatitis and referred to a series of meetings with representatives of Respondent which resulted in an agreement as to the manner in which reference to the CDC study involving chimpanzees (finding 8) could be made.15/ According to Ms. Wills, this was an interim agreement pending the Agency's review of antimicrobial pesticides and, in particular, those claiming effectiveness against hepatitis and AIDS (Tr. 41, 42, 52, 59). Although she could not recall if Respondent was specifically informed the agreement was interim in nature, she contended this was understood from the beginning.16/ The EPA letter, dated September 12, 1986

15/ Tr. 41, 42. This agreement is contained in a letter from Respondent, signed by Dr. Lynch, to Ms. Wills, dated March 15, 1985 (Exh 2) which provides in pertinent part:

> In a 9-month controlled study conducted by the CDC to determine whether the HBV could be inactivated by intermediate to high-level disinfectants, Sporicidin, diluted 1:16, inactivated the hepatitis B virus in 10 minutes.*
>
> *Journal of Clinical Microbiology, Vol. 18, No. 3, p. 535. Five chimpanzees were each challenged with an inoculum treated with a different germicidal chemical. The researchers observed that the small amount of existing direct data, although not conclusive, will have to suffice until a laboratory culture method is developed.

16/ Tr. 60. Mr. Daniel Helfgott, an EPA Environmental Specialist, who participated in promulgating the policy statement of May 28, 1986 (infra, finding 19) testified there was nothing in the policy statement which was inconsistent with the agreement referred to in note 15 (Tr. 29).

(finding 4) informed Respondent that the policy statement published on May 28, 1986 (finding 19, infra) superseded any previous agreements. Ms. Wills pointed out that anti-microbial pesticides presented a special and serious risk to the public, because, although weeds in a field could be seen, microorganisms on an inanimate surface could not (Tr. 43). She stressed that the Agency was obligated not to allow claims against human pathogens, when there was no way of knowing whether a product would kill those microorganisms.17/

19. In May of 1986, EPA issued a policy statement "Advocacy of Pesticide Uses Which Do Not Appear on Registered Pesticide Labels; Amendment to the Statement of Policy," 51 FR 19174, May 28, 1986 (Exh 54). The policy was stated to be an

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17/ A letter, dated January 12, 1984 (Exh 19), from Walter W. Bond, a research microbiologist at CDC and a participant in the chimpanzee study, points out that the only conclusion from the study was that the Hepatitis B Virus did not appear as resistant to disinfectant chemicals as once thought. The letter emphasized that five disinfectants were tested and only one chimpanzee was used for each test and that the data are insufficient to establish the superiority of one chemical over another.

amendment of a policy statement published in 1981[18/] and provided in pertinent part: "(t)his notice informs the public that a person with a financial interest[19/] in the use of an antimicrobial pesticide product, targeted against human pathogens, may not make any claims for the product which differ from those on the product's approved labeling." The rationale for the policy was stated in these terms: "(t)he Agency believes that efficacy claims for antimicrobial products that are not supported by efficacy data submitted in conjunction with that pesticide's registration may foster a false sense of security among health care professionals relying on the product. Additionally, since the presence of the target microorganisms cannot be readily discerned by users, the users cannot easily judge for themselves the

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18/ The mentioned notice (46 FR 51745, October 22, 1981, Exh 78) was precipitated by § 2(ee) of FIFRA, as amended in 1978 (P.L. 95-396), which provides, inter alia, that "(t)he term 'to use any registered pesticide in a manner inconsistent with its labeling' means to use any registered pesticide in a manner not permitted by the labeling, provided that the term shall not include 1. applying a pesticide at any dosage, concentration or frequency less than specified on the labeling, 2. applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling [unless the label states the pesticide may only be used against pests specified on the label], 3. employing any method of application that is not prohibited by the labeling, 4. mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling." The notice informed the public that because § 2(ee) uses are no longer misuse, any person may legally recommend or advertise such uses.

19/ Mr. Helfgott, note 16 supra, testified that persons with financial interests means those who sell, distribute, offer for sale, ship, etc. pesticides (Tr. 16).

effectiveness of that product (see 40 CFR 162.163). Therefore, claims made for antimicrobial products which substantially differ from those made in conjunction with registration could pose a serious health threat" (51 FR 19174). The statement went on to point out that EPA requires the following prior to registering a product with a virucidal label claim: (1) (d)emonstrated recovery of the infective form of the particular virus dried on an inanimate surface and (2) availability and use of suitable assay methods to demonstrate absence of the dried virus after treatment of the surface with the antimicrobial product * *" (Id. at 19175). The policy statement recited that while HBV is a relatively well understood human pathogen, there were only limited experimental data concerning viral recovery and inactivation by disinfectants on hard surfaces. This was attributed to a lack of a suitable assay method for determining whether the infective virus remains on hard surfaces after disinfection. This determination requires an attempt to grow the virus in a host system. The only known nonhuman host system is the chimpanzee, which was stated to be practically unavailable for such experiments. The statement concluded with the assertion that EPA lacks sufficient basis to approve HBV or HTLV-III/LAV virucidal claims for any disinfectant product. It noted, however, that EPA would allow registrants to make HBV and HTLV-III/LAV virucidal claims for sterilizer products when used in accordance with

label directions for the sterilization procedure, and when approved in connection with the specific product registration. On cross-examination, Mr. Helfgott (note 16, supra) testified that there was nothing in the policy statement which defined or expanded on the definition of a claim (Tr. 23).

20. The initial approved label for Sporicidin cold sterilizing solution specified that it was "Sporicidal . Virucidal . Tuberculocidal . Bactericidal . Fungicidal" (Exh 11). The label further provided that it was for medical and dental instruments and equipment in respiratory therapy, surgery, anesthesiology, urology and dentistry. The directions for use stated that for sterilization articles were to be completely immersed for 6 3/4 hours at room temperature. For disinfection, articles were to be completely immersed for 10 minutes at room temperature in a 1 in 16 dilution of the stock solution. The amended labeling, accepted on March 20, 1987 (Exh 7), included the words "pathogenic fungi" after fungicidal and provided, among other things, that "Sporicidin diluted 1:16 can be used and reused for 30 days for 100% hospital level disinfection in 10 minutes against both gram negative and gram positive bacteria, pathogenic fungi, tubercle bacillus and "viruses," i.e., Influenza A/2 Japan; Polio types 1 and 2; Coxsackle B-1; Herpes simplex types 1 and 2, at <u>true room temperature</u> 20°C/68°F (<u>and above</u>), in manual systems (bucket or tray). Labeling accepted on August 26, 1987 (Exh 12) included "Will Not Yellow Hands

when diluted for disinfection," which EPA had previously insisted must be deleted, and labeling for Sporicidin used as a veterinary disinfecting solution. Labeling approved on September 24, 1987 (Exh 15), provided, inter alia, that Sporicidin when used or reused as directed as a chemical sterilant completely kills Hepatitis B and HTLV-III/LAV AIDS viruses at the full range of room temperatures 20°C/68°F (and above).

21. The label for Permacide, EPA Registration No. 8383-4, approved October 25, 1972 (Exh 70), provided, inter alia, that Permacide is a germacidal compound which kills most disease and odor-producing bacteria and fungi on hard surfaces. The product was indicated to be virucidal against influenza A virus (Japan 305/57), to kill the organism that causes Athlete's Foot and to be tuberculocidal against both human and bovine (animal) strains of the tubercle bacillus on environmental surfaces. Revised labeling for Permacide (Exh 71) states that it provides continuous residual activity for over six months in the presence of adequate moisture, that it passes the rigid AOAC efficiency standards for hospital and institutional type spray disinfectant and that the spray provides 100% kill of most disease and odor-causing organisms (listing examples) at 20°C.

21. Dr. Curtis Lynch, medical director and Respondent's sole witness, testified that the AIDS virus was considered to be rather fragile and that he understood this was the reason EPA had not established test protocols [for disinfectants against

the virus] (Tr. 187-88). He pointed out, however, that the virus can live from five to seven days on dry surfaces and that during this period, it was not possible to reconstitute the virus so that the virus grew to an infective dose.20/ He understood this was one of the main reasons EPA has not accepted data [on the effectiveness of disinfectants against the virus].21/ Dr. Lynch testified that he was acquainted with Dr. Favero of the CDC who is regarded as an authority on recommended guidelines for hospitals.22/ An article from the Association of Operating Nurse's Journal (Respondent's Exh 10), with which Dr. Lynch is also familiar, quotes Dr. Favero as stating that no operating room protocols need to be changed because an AIDS patient is having surgery and that if a spill occurs during such a procedure, a cleaning agent that is labeled as a hospital disinfectant and tuberculocidal would be adequate.

20/ By letter, dated December 18, 1986 (Exh 6), Respondent was informed that submitted data were not adequate to support the effectiveness of the product (EPA Registration Nos. 8383-3, -4 and -5) against the AIDS virus, HTLV-III (H9) on inanimate surfaces. The reasons for this conclusion were detailed on an enclosed technical review document applicable to Sporicidin (EPA Registration No. 8383-5) which stated, inter alia, that no data were made available to assess the effect of controlled drying conditions on different strains of the AIDS virus from inanimate surfaces and the technique employed to "resuspend" the virus inoculum in the disinfectant was not acceptable. Respondent had been given similar advice in the past (letters, dated May 17, 1985 and May 2, 1986, Exhs 9 & 10).

21/ See finding 19. According to Dr. Lynch, Bionetics has now received EPA acceptance of its test protocols with some amendments (Tr. 186).

22/ Dr. Favero was also a participant in the CDC "chimpanzee study" (finding 8).

22. Dr. Lynch denied that the Bionetics' studies involving the effectiveness of Sporicidin and Permacide against the AIDS virus (finding 9 and 12) were included in general mailings to hospitals and health care professionals (Tr. 185). He acknowledged, however, bringing the studies to D.C. General at the time of various visits, he recounted three, to the Hospital, one of which was for the purpose of participating in a seminar on waste management and disinfectants. He denied saying that Respondent had EPA approval for use of Sporicidin as a disinfectant [against Hepatitis B and AIDS viruses], explaining that it was used as a sterilant, not a one to sixteen dilution [for use as a disinfectant].23/ He stated that, to his knowledge, EPA had never informed Respondent that the agreement as to the manner of alluding to the CDC study (note 15, supra) was interim in nature (Tr. 191-92). Because of what he described as a "real mania" in the medical community, he asserted that no one can discuss sterilants or disinfectants at a national or local meeting without AIDS coming up (Tr. 186). Asked what was the company's policy if inquiries were made as to the effectiveness of its products against AIDS, Dr. Lynch replied that the policy was somewhat dictated by discussions with Ms. Wills' group (finding 18). He noted that information found with Sporicidin

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23/ Tr. 186. This denial is supported in part by the testimony of Ms. Wilson, a nurse at the Hospital (finding 17).

literature would [probably] be considered labeling, but that professionals sharing research data were a different matter.

23. Ms. Spencer, finding 3, testified that firms which were no longer making "offending claims" were not charged with violations (Tr. 151-52). She explained the computation of the proposed penalty against Respondent. For this purpose, she used the guidelines for the assessment of civil penalties under § 14(a) of FIFRA, 39 FR 27711 et seq. (July 31, 1974) (Tr. 140-41; Civil Penalty Assessment Worksheet, Exh 79). She stated that the penalty was based on two factors: the severity of the violation and the size of the company. Category (Charge Code) E17 of the guidelines covers claims differing from those accepted in connection with the product's registration, with the maximum penalty of $5,000 imposed where adverse effects were highly probable. Category E23 covers misbranding in that the labeling bears a statement which is false or misleading (Id. at 27722). Because human pathogens are involved, Ms. Spencer determined that the likelihood of harm was high. She made this determination for all three counts of the amended complaint and noting that the Dun & Bradstreet Report (Exh 80) indicated Respondent had declined all financial information, assessed the maximum penalty of $5,000 for each count.

C O N C L U S I O N S

1. The search of Respondent's offices on August 21, 1987, must be regarded as a federal search even though the warrant authorizing the search was issued under District of Columbia law. Evidence seized during such search, which was not proper under FIFRA § 9, is not admissible against Respondent herein.

2. Respondent made claims as part of the distribution or sale of the pesticide Sporicidin Cold Sterilizing Solution (EPA Registration No. 8383-5), which substantially differ from claims accepted in connection with the product's registration and thus violated § 12(a)(1)(B) of the Act as charged in Count I of the complaint.

3. Although there is no evidence of sales of Sporicidin Brand Disinfectant Spray (Permacide) (EPA Registration No. 8383-4), the record shows that the product was distributed to a limited extent and that Respondent made claims for the product as a part of its distribution differing substantially from those accepted as a part of its registration. Respondent has thus violated § 12(a)(1)(B) of the Act as alleged in Count II of the complaint.

4. Complainant has not established that labeling for Sporicidin Cold Sterilizing Solution was false or misleading in any particular and thus has not proven misbranding as charged in

Count III of the complaint. Count III of the complaint will be dismissed.

5. For the violation referred to in conclusions 1 and 2, a penalty of $10,000 will be assessed against Respondent.

D I S C U S S I O N

I. Legality of Inspection

As noted at the outset of this decision (ante at 3, 4), the order, dated February 22, 1988, denied Respondent's motion to suppress evidence seized during the inspection of its offices on August 21, 1987, upon the ground the search was proper under D.C. law and regulation even though the search could not be justified under FIFRA.[24/] Testimony at the hearing, however, revealed that Mr. Greenleaf carries inspector's credentials issued by both EPA and the District of Columbia Government and that he could be regarded as an employee of both agencies (finding 5). In view thereof, and of the fact that the inspection of Respondent's premises was initiated by EPA and the D.C. Government, Department of Consumer and Regulatory Affairs (DCRA) has primary FIFRA enforcement responsibility in the District (finding 4), it is concluded that

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24/ This was because the search purported to be conducted in part under FIFRA § 9 and evidence pesticides were held for distribution or sale at the premises named in the warrant was stale and outdated. Although the notices of inspection didn't specifically refer to FIFRA § 9, the notices did refer to establishments or other places where pesticides were held for distribution or sale and to § 12(a)(2)(B), which, inter alia, makes it unlawful for any person to refuse to allow an inspection pursuant to §§ 8 or 9.

the search must be regarded as federal and subject to federal standards.25/ Although it might be argued that the good faith exception to the requirement that warrants be issued and executed in strict accordance with requirements of statute and the Constitution is applicable, literature collected by Mr. Greenleaf at D.C. General Hospital does not differ substantially from that seized during the inspection on August 21, 1987,26/ and none of the conclusions in this decision is based upon the latter evidence.

II. Claims for the Effectiveness of Sporicidin Cold Sterilizing Solution and Permacide Brand Disinfectant Spray

Section 12(a)(1)(B) of the Act provides:

"(a) In General.--

(1) Except as provided by subsection (b), it shall be unlawful for any person in any State to distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person--

* * *

(B) any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 3;

* * * *."

25/ See, e.g., United States v. Martin, 600 F.2d 1175 (5th Cir. 1979) (search participated in by agents of DEA, under a warrant issued by a state court, was a federal search and federal standards were applicable).

26/ Although Respondent objects to the inspections at D.C. General (Proposed Findings and Conclusions and Supporting Brief at 12-14), it is clear that Respondent lacks standing to question the legality of inspections at the Hospital. See Jones v. United States, 362 U.S. 257 (1960) (only victim of an invasion of privacy may seek to suppress relevant evidence).

The evidence established that Respondent's representative, Dr. Lynch, brought literature to D.C. General Hospital, including specifically the Bionetics' reports referred to in findings 9 & 12, in the early part of 1987.27/ For ease of reference, the discussion herein will be limited to the Bionetics' reports. Leaving aside for the moment the definition of a claim as used in § 12(a)(1)(B) of the Act, it is clear that these reports contain statements that Sporicidin and Permacide were effective when used as disinfectants against the AIDS virus (findings 9 and 12). It is equally clear that the approved labels for the mentioned products do not provide that the products are effective as disinfectants against the AIDS virus and that EPA has never approved labels making such assertions (findings 18, 20 and 21).

The remaining questions are whether the statements in the Bionetics' reports constitute claims within the meaning of the Act and whether such claims were made as part of Sporicidin's distribution or sale.

27/ Findings 12, 13, 17 & 22. This was long after publication of the policy statement on May 28, 1986 (finding 19) and EPA's issuance of letters, dated June 30 and September 12, 1986, informing Respondent that claims made in collateral literature for the effectiveness of Sporicidin against the Hepatitis B and HTLV III/LAV (AIDS) viruses were unacceptable. Accordingly, as to this literature, there can be no issue of Respondent having ceased making certain assertions as to the effectiveness of its products in advertisements as stated in its letter, dated July 10, 1986 (note 3, supra). This also refutes Respondent's contention that its activities in advertising the effectiveness of its products against the AIDS virus were not current.

The word "claims" appears twice in § 12(a)(1)(B), the second referring to "claims made for it [the pesticide] as part of the statement required in connection with its registration under section 3;." Section 3(c) of the Act provides that "(e)ach applicant for registration of a pesticide shall file with the Administrator a statement which includes--* * (c) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use; * *." It is reasonable to regard "claim" as being used in its common, ordinary sense and to have the same meaning in each of the cited sections. Among the definitions of "claim" is an "assertion, statement or implication (as to value, effectiveness, qualification, eligibility) often made or likely to be suspected of being made without adequate justification."28/ It is therefore concluded that the assertions in the Bionetics' reports as to the effectiveness of Sporicidin and Permacide against the AIDS virus are claims within the meaning of FIFRA § 12(a)(1)(B). Citing a statement in Assistant Administrator Moore's letter to Senator Daschle that an EPA-wide "working group" had been established to focus on the development of a definition of

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28/ Webster's Third New International Dictionary (1967).

the term "claim," as used in FIFRA § 12(a)(1)(B),29/ Respondent argues in effect that it is unfair to seek to impose a penalty where there are reasonable grounds for different conclusions as to what constitutes a "claim" and the guidelines in this respect, envisaged by Dr. Moore, have not been issued (Brief at 8, 9). This argument would have merit, if EPA were attempting to enforce or apply an unusual or expanded definition of the term "claim." Because, however, the definition of a "claim" applied here is the ordinary dictionary definition, Respondent may properly be charged with notice of this meaning, notwithstanding EPA's apparent recognition of the desirability of clarifying the meaning of the term in some respects.

Having concluded that the Bionetics' reports may properly be regarded as making claims within the meaning of FIFRA,30/ the

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29/ The mentioned statement (Dr. Moore's letter to Senator Daschle, dated July 29, 1987, Respondent's Exh 7, at 2-3) provides:

> "Finally, on this issue, I have established an EPA-wide workgroup to deal with advertising. Among other things, I expect this group to focus on development of a definition of the term "claim", as used in section 12(a)(1)(B) of FIFRA, and to attempt to establish a list of statements which EPA will consider as claims that cannot be made by any registrant under any circumstances unless supported by efficacy data, and a list of other statements which we conclude can be treated not as claims but as information to users so long as such information is presented in a truthful and non misleading manner."

30/ Although Respondent argues the Bionetics' reports are those of an independent laboratory (Reply Brief at 2), Respondent in effect adopted the studies as its own by disseminating the reports.

next question is whether the claims for Sporicidin were made as part of the product's distribution or sale. Complainant asserts that literature making efficacy claims for its products was distributed by Respondent's agent at the same time the products were being used at D.C. General Hospital and argues that it has thereby established a prima facie case of violations of §§ 12(a)(1)(B) and 12(a)(1)(E) as alleged in the complaint (Trial Brief at 14, 15). Respondent contends that EPA has interpreted the phrase "as part of its distribution or sale" in § 12(a)(1)(B) as meaning that the literature making the claims accompanied the product as it was sold or distributed (Brief at 4). For this assertion, it cites an EPA letter, dated May 18, 1984, signed by Ms. Wills, which, carefully read, does not support its position.31/ This is because Respondent overlooks or ignores the proviso "or if the advertisement contains claims which differ substantially from those made at the time of registration."

The order, dated February 22, 1988, concluded that FIFRA § 12(a)(1)(B) was not a general proscription on advertising claims

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31/ The paragraph relied upon (Respondent's Exh 8 at 2) provides:

> "First, it should be noted that the Agency does not regulate advertising per se. Advertising of a pesticide product becomes subject to FIFRA only if the advertisement comes within the meaning of labeling because it accompanies the product as it is sold or distributed, or if the advertisement contains claims which differ substantially from those made at the time of registration. Promotional material distributed to the public apart from the pesticide product, is not considered labeling, even though it makes claims for the product."

for a pesticide differing substantially from those accepted in connection with the product's registration. The primary reason for this conclusion was that effect must be given to the qualifying words "as part of its [the pesticide's] distribution or sale," which were contrasted with § 12(2)(B) making it unlawful for any person who is a registrant, wholesaler, dealer, retailer or other distributor to advertise a product registered for restricted use without giving the classification of the product and § 13(b)(1)(E) which authorizes an in rem action in district court for the seizure of a pesticide, if, inter alia, any of the claims made for it or any of the directions for its use differ in substance from representations made in connection with its registration.32/ Although the conclusion that the cited sections are not coextensive is compelling,33/ Complainant asserts that claims made for a

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32/ The substance of § 13(b)(1)(E) appears to have been lifted from § 3 of FIFRA of 1947 (Public Law 104, 61 Stat 163, June 25, 1947), providing in pertinent part:

> Sec.3. (a) It shall be unlawful for any person to distribute, sell, or offer for sale in any State, Territory or in the District of Columbia, * * *:
>
> (1) Any economic poison which has not been registered pursuant to the provisions of section 4 of this Act, or any economic poison if any of the claims made for it or any of the directions for its use differ in substance from the representations made in connection with its registration, * * *.

33/ In addition to authority cited in the February 22 order, see INS v. Cardoza-Fonseca, 480 U.S. ____, 94 L.Ed 2d 434 (1987) at 448: "Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." (citations omitted).

pesticide as part of its distribution or sale encompasses claims made in promotional literature and advertising (Trial Brief at 31). It is argued that the plain meaning of the statute supports this interpretation. To the extent that the statute might be regarded as ambiguous, however, Complainant relies on the familiar principle that an agency's interpretation of a statute it is empowered to administer is entitled to deference and asserts that this is especially true where the agency's interpretation has been long standing and consistent.34/ FIFRA being remedial in nature, Complainant says that the Act should be liberally construed to effectuate its intended purpose.

Reference to the dictionary, however, affords some difficulty for Complainant's argument, because "part" is defined, inter alia, as an "essential portion" or an "integral element"35/ and it may well be questioned whether any advertising, let alone that shown here, is an essential portion or an integral element of the

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34/ Complainant relies on policy statements published October 22, 1981 (note 18, supra), and May 28, 1986 (finding 19), to support its contention this is a consistent and long-standing interpretation. Complainant also relies on a proposed interpretative rule Pesticide Advertising (51 FR 24293, July 3, 1986), which would make it unlawful for any person who sells, holds for sale, or distributes pesticides to place or sponsor advertisements of, inter alia, registered pesticides for unregistered uses, except to the extent the advertisement is a permitted one concerning a section 18 exemption or a section 24(c) registration.

35/ Webster's Third New International Dictionary (1967).

pesticide sales at issue.36/ Moreover, under Complainant's view, the statute appears to have the same meaning with or without the phrase "as a part of its distribution or sale."37/ In an apparent effort to overcome this hurdle, Complainant argues that the most logical reason for the addition of the quoted phrase to § 12(a)(1)(B) is that Congress wanted to ensure that enforcement of § 12(a)(1)(B) would be against registrants, distributors and sellers rather than users (Trial Brief at 35-39). This contention also begets some difficulty, because, as recognized by EPA's own witness, Mr. Helfgott,38/ activities and persons subject to § 12 (a) are set forth in § 12(a)(1), that is "* * it shall be unlawful for any person in any State to distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver to any person * *." Although a person receiving a pesticide arguably could include a user, users

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36/ It is generally accepted that, absent compelling reasons to the contrary which are not present here, a word should be accorded the same meaning each time it appears in a statute and it is evident that defining "part" as in the text is fully consonant with "part" the second time it appears in § 12(a)(1)(B), i.e., "an essential portion or integral element" "of the statement required in connection with its registration under section 3."

37/ Notwithstanding the fact that § 3(a)(1) of FIFRA of 1947 did not contain the phrase "as a part of its distribution or sale" (note 32, supra), Complainant relies on interpretative notices issued by the Department of Agriculture, since rescinded, to support its contention EPA's interpretation of § 12(a)(1)(B) has been consistent and long-standing.

38/ Mr. Helfgott testified that § 12(a)(1) specified to whom the section applied, while § 12(a)(1)(B) [defined] a specific violative act (Tr. 20, 21).

are unlikely to be offering pesticides for sale or distributing pesticides.39/ Accordingly, the phrase "as a part of its distribution or sale" appears redundant, if the phrase has the purpose attributed to it by Complainant.

The foregoing notwithstanding, it is unnecessary to accept Complainant's argument that FIFRA confers upon EPA broad powers to regulate pesticide advertising in order to decide this case. This is because the record is clear that the Bionetics' reports, which we have already decided made claims within the meaning of the Act for the pesticides here concerned, were brought to the Hospital by Respondent's agent, Dr. Lynch, at a time when Sporicidin was being used therein. The record is also clear that Dr. Lynch introduced Hospital personnel to Sporicidin, brought Sporicidin to the Hospital and discussed the product with Hospital personnel on several

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39/ See, e.g., § 2(e) which provides in pertinent part:

(e) Certified Applicator, Etc.--

(1) Certified applicator.-- * * Any applicator who holds or applies registered pesticides, or use dilutions of registered pesticides consistent with section 2(ee) of this Act, only to provide a service of controlling pests without delivering any unapplied pesticides to any person so served is not deemed to be a seller or distributor of pesticides under this Act.

If applicators are not deemed to be sellers or distributors of pesticides, a fortiori would users not be. See Hygienic Sanitation Company, Inc., I.F. & R. Docket No. III-184C (Initial Decision, September 18, 1979), which concluded applicators were not sellers or distributors prior to the amendment of FIFRA (Federal Pesticide Act of 1978), which added the quoted language.

occasions.40/ Although it is true that Sporicidin is used by the Hospital, not because of any claims for its effectiveness against the AIDS virus, but merely because CDC recommends use of high-level disinfectants (findings 12 and 17), it is reasonable to conclude that the only purpose for bringing the Bionetics' reports and other literature to the hospital was to induce the continued sale and use of Respondent's products. There is no evidence of any other purpose for distributing the reports and, in any event, it is reasonable to place the burden of proof in that respect on Respondent. Under these circumstances, the Bionetics' reports may reasonably be considered a part [an integral element] of Sporicidin's distribution or sale.

While far more tenuous, it is concluded that Complainant has also established a violation of § 12(a)(1)(B) with respect to Permacide. The record reflects that Respondent introduced Permacide to Hospital personnel within the past year (finding 17). Permacide is a spray disinfectant and there is no evidence that it is or can be used as a sterilant. The approved label for Permacide allowed certain virucidal and tuberculocidal claims for the product (finding 21), but definitely did not allow claims for the pesticide's effectiveness against the AIDS virus. While there is no evidence of

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40/ Finding 17. Contrary to Complainant's assertions, however, there is no evidence that the oral claims made by Dr. Lynch as to the effectiveness of Sporicidin against the AIDS virus related to the product's use as a disinfectant. Rather, the record reflects that these oral claims concerned Sporicidin's use as a cold sterilant (findings 17 and 22), and, as Complainant well knows, such claims are not a violation of § 12(a)(1)(B) or any other provision of FIFRA.

any oral claims for Permacide, it is clear the Bionetics' reports made such claims for both Sporicidin and Permacide.41/ There are, however, no purchase orders, shipping documents or invoices in the record reflecting the sale by Respondent and the purchase or receipt by the Hospital of Permacide. Evidence of Respondent's distribution of Permacide shown by this record then consists of Ms. Teal's testimony that Permacide was at the hospital and the can of Permacide displayed at the hearing (note 12, supra). This is, of course, thin evidence upon which to base a finding that the claim in the Bionetics' reports as to Permacide's effectiveness against the AIDS virus was made as part of the product's distribution. Nevertheless, absent evidence to the contrary, it is reasonable to assume that the only purpose of furnishing the report to the Hospital was to induce the purchase and use and thus the distribution of Permacide. As noted above in connection with Sporicidin, it is reasonable to place the burden of proof in this respect on Respondent, because any other rule would place an impossible burden on Complainant and frustrate the purpose of the Act, which is to alleviate health risks attributable to unsubstantiated and possibly misleading claims for the effectiveness of disinfectants.

41/ Evidence of claims for Permacide is limited to the Bionetics' report, because literature seized during the inspection of Respondent's offices on August 21, 1987, has been determined to be inadmissible.

M I S B R A N D I N G

Count III of the complaint alleges that shipments of Sporicidin made to D.C. General Hospital on June 5, July 31 and September 21, 1987, were misbranded in that labeling accompanying the product made claims for its effectiveness against the AIDS virus which were false and misleading. The Act defines labeling as follows:

> "(p) Label and Labeling.--
>
> "(1) Label.--The term 'label' means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.
>
> "(2) Labeling.--The term 'labeling' means all labels and all other written, printed, or graphic matter--
>
> "(A) accompanying the pesticide or device at any time; or
>
> "(B) to which reference is made on the label or in literature accompanying the pesticide or device, * * *."

Additionally, "[a] pesticide is misbranded, if:

> "(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular; * * *."
> (§ 2(q)(1)(A)).

Complainant asserts, accurately enough, that labeling which makes claims for a pesticide which substantially differ from those accepted in connection with the product's registration may be deemed false or misleading (Trial Brief at 46). Complainant also contends, however, that the mere fact the Bionetics' reports and

promotional material making claims for or otherwise referring to Respondent's products were present at the Hospital at the same time as the products indicates the promotional material accompanied the product and thus constitutes "labeling" within the meaning of the Act (Trial Brief at 44, 45). This contention is rejected. The dictionary defines "accompanying" to mean, inter alia, to "add or join to"[42/] and the fact the promotional materials were present at the same location as the products does not satisfy this common understanding of "accompany." Acceptance of Complainant's position would mean that advertising materials coincidentally present at the same location as the pesticides would also be considered labeling and would largely eliminate any distinction between written or collateral advertising materials and labeling. Moreover, as Respondent points out, EPA has previously taken the position that promotional material distributed to the public apart from the pesticide product is not considered labeling (Will's letter, note 31, supra). Although Complainant cites 40 CFR § 162.4(b)(1) as directing the Agency to consider labeling as including "collateral advertising" in determining whether a product is a pesticide, the cited provision clearly distinguishes between labeling and collateral advertising

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42/ Webster's Third New International Dictionary (1967).

materials.43/ By definition, "collateral materials" are materials other than, or in addition to, labeling. Complainant rejected Respondent's attempt to equate claims with labeling (Trial Brief at 39-41) and, for the reasons stated, Complainant's attempt to expand the meaning of labeling is also rejected.

If the foregoing be regarded as doubtful or subject to question, it is nevertheless clear that no separate count or penalty for the alleged misbranding can be justified. This is because there is no evidence or even an allegation that the promotional materials physically accompanied the products and thus, there are no separate or independent acts, beyond those shown for Counts I and II, to support the violation alleged. Count III of the complaint will be dismissed.

P E N A L T Y

As indicated (finding 23), the proposed penalty of $5,000 for each of the three counts in the complaint was determined in accordance with the FIFRA civil penalty guidelines (39 FR 27711, July 31, 1974). The statutory maximum penalty for each offense was proposed

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43/ Section 162.4(b)(1) provides:

(b) Products considered to be pesticides. A product will be considered to be a pesticide if:

(1) Claims or recommendations for use as a pesticide are made on the label or labeling of the product including, but not limited to, collateral advertising, such as publications, advertising literature which does not accompany the product, or advertisements by radio or television;

* * * *.

based upon the determination that adverse effects from the violations here concerned were highly probable. There is no evidence in the record of Respondent's sales, revenues or financial condition and Complainant is apparently of the view that the burden of proof in such matters is upon Respondent.

Leaving aside for the moment questions as to the size of Respondent's business and the effect of the proposed penalty on its ability to continue in business, § 14(a)(4) of the Act requires, inter alia, that the "gravity of the violation" be considered in determining an appropriate penalty. Gravity of the violation is usually considered from two aspects: gravity of the harm and gravity of the misconduct.44/ Because of the uses of the pesticides at issue and the obvious human health risks from users' acceptance of unsubstantiated claims for the products' effectiveness against the AIDS virus, it is concluded that the gravity [likelihood] of harm is high and the determination that adverse effects from the violations are highly probable is affirmed. Because the record shows that Respondent was repeatedly informed that claims made for its products in collateral literature and advertising materials, in addition to those submitted as part of the products' registration, were unacceptable, the gravity of

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44/ See, e.g., High Plains Cooperative, Inc., Docket No. I.F. & R.-VIII-198C (Initial Decision, June 29, 1987) presently on appeal to the Administrator.

misconduct is also high or serious. Consideration of the above factors then, leads to the conclusion that imposition of the maximum penalty is fully warranted.

The Act also requires that the size of Respondent's business and the effect of the penalty on its ability to continue in business be considered and this is more difficult, because there is no evidence as to these matters in the record. Katzson Bros., Inc. v. U.S. EPA, 839 F.2d 1396 (10th Cir. 1988), wherein a penalty allegedly based on the FIFRA guidelines was set aside, would seem to have laid to rest any notion that factors, which the statute requires be considered in determining an appropriate penalty, may be ignored or glossed over in favor of penalty guidelines. Moreover, the Rules of Practice (40 CFR § 22.24) make it clear that the burden of demonstrating the appropriateness of the penalty is on Complainant.45/

The foregoing requirements exist in some tension with the general rule that a party in possession of relevant evidence normally has the burden of production as distinguished from the burden of proof. See the discussion by the Judicial Officer in Kay Dee Veterinary, Division of Kay Dee Feed Company, FIFRA Appeal No. 86-1 (Order, October 27, 1988). Although the FIFRA penalty guidelines

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45/ See also Bosma v. U.S. Department of Agriculture, 754 F.2d 804 (9th Cir. 1984) (Department of Agriculture as proponent of an order within meaning of Administrative Procedure Act [5 U.S.C. 556(d)] was required to produce evidence that proposed penalty was reasonable).

provide that the burden of providing information that a proposed penalty would have an adverse effect on Respondent's ability to continue in business is on Respondent, the guidelines are not binding (40 CFR § 22.27(b)) and obviously cannot prevail over contrary provisions of statute, e.g., the Administrative Procedure Act, or the Rules of Practice.

In Kay Dee Veterinary, supra, the Judicial Officer stated that was not clear whether the rule in Bosma (note 45, supra) was applicable to cases under FIFRA, but held that it was unnecessary to decide that question, because there was sufficient evidence of Kay Dee's financial condition in the record to reach a decision (Slip Opinion at 10, note 15). Kay Dee was held to have demonstrated that imposition of the penalty proposed would adversely effect its ability to continue in business and the penalty was reduced from $30,000, proposed in the complaint, to $1,200. Cf. Buerge Feed and Seed, FIFRA Appeal No. 88-1, (Final Decision, August 31, 1988) (appeal of default order, where Respondent submitted no evidence to substantiate its claim imposition of penalty might render it unable to continue in business).

Section 22.15(a) of the Rules of Practice[46/] (40 CFR § 22.15 (a)) provides that "[w]here respondent * * (2) contends that the amount of the penalty proposed in the complaint * * is inappropriate; * * * he shall file a written answer to the complaint with the Regional Hearing Clerk." Section 22.15(b) of the Rules requires that an answer state "* * (2) the facts which respondent intends to place at issue, * *." In view thereof, Respondent's failure to raise any issue as to its financial condition makes reasonable the presumption in the penalty guidelines "* * that assessment of a civil penalty will not affect the ability of the person charged to continue in business" (39 FR 27712). While it maybe more tenuous to make such an assumption as to the size of Respondent's business, Respondent has long had access to a copy of the civil penalty worksheet (Exh 79), which

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46/ Section 22.15 "Answer to the complaint" provides:

(a) General. Where respondent (1) contests any material fact upon which the complaint is based; (2) contends that the amount of the penalty proposed in the complaint or the proposed revocation or suspension, as the case may be, is inappropriate; or (3) contends that he is entitled to judgment as a matter of law, he shall file a written answer to the complaint with the Regional Hearing Clerk. Any such answer to the complaint must be filed with the Regional Hearing Clerk within twenty (20) days after service of the complaint.

(b) Contents of the answer. The answer shall clearly and directly admit, deny or explain each of the factual allegations contained in the complaint with regard to which respondent has any knowledge. Where respondent has no knowledge of a particular factual allegation and so states, the allegation is deemed denied. The answer shall also state (1) the circumstances or arguments which are alleged to constitute the grounds of defense, (2) the facts which respondent intends to place at issue, and (3) whether a hearing is requested.

indicates it was placed in Category V, gross sales over one million dollars, for penalty computation purposes and has raised no issue or objection thereto. Under these circumstances, imposition of the maximum penalty based on sales of over one million dollars is considered appropriate.

O R D E R[47/]

Respondent, Sporicidin International, having violated § 12 (a)(1)(B) of the Act as charged in Counts I and II of the complaint, a penalty of $10,000 is assessed against it in accordance with § 14(a) of FIFRA. Payment of the full amount of the penalty shall be made by sending a certified or cashier's check payable to the Treasurer of the United States to the following address within 60 days of the receipt of this order:

Hearing Clerk
EPA - Washington Headquarters
P.O. Box 360277M
Pittsburgh, Pennsylvania 15251

Evidence seized during the search of Respondent's offices on August 21, 1987, is suppressed and Count III of the complaint, charging misbranding, is dismissed.

Dated this 1st day of November 1988.

Spencer T. Nissen
Administrative Law Judge

47/ Unless appealed in accordance with Rule 22.30 (40 C.F.R. Part 22) or unless the Administrator elects sua sponte to review the same as therein provided, this decision will become the final order of the Administrator in accordance with Rule 22.27(c).