



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 4  
ATLANTA FEDERAL CENTER  
61 FORSYTH STREET  
ATLANTA, GEORGIA 30303-8960

4APT-PTSB

**OCT 09 2007**

Federal Express – Overnight Delivery

Ms. Catherine Trinkle  
Senior Counsel  
Schering-Plough Corporation  
2000 Galloping Hill Road  
Kenilworth, NJ 07033

SUBJ: Docket No. FIFRA-04-2007-3027(b)  
Schering-Plough Healthcare Products, Inc.

Dear Ms. Trinkle:

Enclosed is a copy of the ratified Consent Agreement and Final Order (CAFO) in the above-referenced matter. The original CAFO has been filed with the Regional Hearing Clerk and served on the parties as directed in Section 22.6 of the Consolidated Rules of Practice, 40 CFR Part 22.

Please make note of the provisions in Section IV of the Final Order, with respect to payment of the assessed penalty of \$40,950, which is due within 30 days from the effective date of the CAFO. If paying by cashier's or certified check, we request that the payment be identified by writing the company name and docket number on the face of the check.

Penalty payment questions should be directed to Ms. Lori Weidner either by telephone at (513) 487-2125 or by written correspondence to her attention at the U.S. EPA, Cincinnati Accounting Operations address identified in Section 27 of the CAFO. Should you have any questions about your compliance status in the future, please call me or Ms. Melba Table at (404) 562-9086.

Sincerely,

A handwritten signature in cursive script that reads "Joanne Benante".

Joanne Benante  
Chief  
Pesticides and Toxic  
Substances Branch

Enclosures

cc: Kathy Booker, TDA

UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY  
ATLANTA, GEORGIA

RECEIVED  
EPA REGION IV  
2007 OCT -9 PM 2:25  
HEARING CLERK

In the Matter of: )  
 )  
Schering-Plough HealthCare ) Docket No. FIFRA-04-2007-3027(b)  
Products, Inc. )  
 )  
Respondent. )  
\_\_\_\_\_ )

CONSENT AGREEMENT AND FINAL ORDER

I. Nature of the Action

1. This is a civil penalty proceeding pursuant to Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. § 136l(a) (hereinafter "FIFRA"), and pursuant to the Consolidated Rules of Practice Governing Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (Consolidated Rules), 40 CFR Part 22. Complainant is the Director of the Air, Pesticides, and Toxics Management Division, United States Environmental Protection Agency, Region 4 (EPA). Respondent is Schering-Plough HealthCare Products, Inc.
2. Complainant and Respondent have conferred for the purpose of settlement pursuant to 40 CFR § 22.18 and desire to resolve this matter and settle the allegations described herein without a formal hearing. Therefore, without the taking of any evidence or testimony, the making of any argument, or the adjudication of any issue in this matter, and in accordance with 40 CFR § 22.13(b), this Consent Agreement and Final Order (CAFO) will simultaneously commence conclude this matter.

## II. Preliminary Statements

3. The authority to take action under Section 14(a) of FIFRA, 7 U.S.C. § 136l(a), is vested in the Administrator of EPA. The Administrator of EPA has delegated this authority under FIFRA to EPA Region 4 by EPA Delegation 5-14, dated May 11, 1994.
4. Pursuant to 40 CFR § 22.5(c)(4) the following individual represents EPA in this matter and is authorized to receive service for EPA in this proceeding:

Melba Table  
Pesticides Management Section  
U.S. EPA - Region 4  
61 Forsyth Street  
Atlanta, Georgia 30303-8960  
(404) 562-9086.

5. Respondent is Schering-Plough HealthCare Products, Inc., a Delaware corporation, located at 3030 Jackson Ave., Memphis, TN 38151. The following individual represents Schering-Plough HealthCare Products, Inc. in this matter and is authorized to receive service for Schering-Plough HealthCare Products, Inc. in this proceeding:

Catherine A. Trinkle  
Senior Counsel  
Schering-Plough Corporation  
200 Galloping Hill Road  
Kenilworth, New Jersey 07033  
(908) 298-2254.

6. Respondent is a "person" as defined by Section 2(s) of FIFRA, 7 U.S.C. § 136(s), and as such is subject to FIFRA and the regulations promulgated thereunder.
7. On or about April 16, 2006, an authorized representative of the EPA conducted an inspection at CVS Pharmacy, 902 N. J. K. Powell Blvd., Whiteville, NC 28472.

8. During the aforementioned inspection, the product "Dr. Scholl's Air-Pillo Cushioning Comfort Insoles with Antimicrobially Treated Topcloth," was identified as being produced and distributed by the Respondent.
9. On or about October 11, 2006, an authorized representative conducted an inspection at Schering-Plough HealthCare Products, Inc., 3030 Jackson Ave., Memphis, TN 38151.
10. The inspector documented the following ten shipments of Air-Pillo Cushioning Comfort Insoles Antimicrobially Treated Topcloth:

Ship Date	Invoice	Quantity	Customer
10/3/06	0017168094	360	Ralph's Grocery Co.
10/3/06	0017168465	108	Target #551
10/4/06	0017169284	2160	Webco-Hale
10/4/06	0017168117	180	Frankel, Inc.
10/5/06	0017168656	612	Kmart Corp. Warehouse 8273
10/5/06	0017169184	360	Eckerd Drug Warehouse
10/6/06	0017165001	1584	Corporation Inter SA
10/6/06	0017169791	288	Duane Reade
10/9/06	0017169947	144	C S Warehouse Services- Dunmore
10/10/06	0017170293	576	Food Lion.

11. Dr. Scholl's Air-Pillo Cushioning Comfort Antimicrobially Treated Topcloth is a pesticide as defined in Section 2(u) of FIFRA, 7 U.S.C. § 136(u), which includes any substance or mixture or substances intended for preventing, destroying, repelling, or mitigating any pest.
12. Furthermore, Dr. Scholl's Air-Pillo Cushioning Comfort Antimicrobially Treated Topcloth product is an antimicrobial pesticide as defined in Section 2(mm) of FIFRA, 7 U.S.C. § 136(mm).

13. A “pest” is defined in Section 2(t) of FIFRA, 7 U.S.C. § 136(t), as any insect, rodent, nematode, fungus, weed, or any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other microorganisms on or in living man or other living animals) which the Administrator declares to be a pest under Section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1).
14. An “antimicrobial pesticide” is defined in Section 2(mm) of FIFRA, 7 U.S.C. § 136(mm), as a pesticide that is intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms.
15. Respondent “distributes or sells” pesticides. The term “to distribute or sell” as defined by Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), includes to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, or release for shipment
16. At the time of the aforementioned inspections, the Dr. Scholl’s Air-Pillo Cushioning Comfort Insoles Antimicrobially Treated Topcloth was not registered as a pesticide with EPA.
17. It is unlawful according Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), for any person to distribute or sell to any person any pesticide that is not registered under Section 3 of FIFRA, 7 U.S.C. § 136a.
18. EPA alleges the Respondent violated Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), on ten separate occasions and is therefore subject to the assessment of civil penalties under Section 14 of FIFRA, 7 U.S.C. § 136l.

19. EPA alleges that at the time of the aforementioned inspections, the label on Dr. Scholl's Air Pillo Cushioning Comfort Antimicrobially Treated Topcloth indicated that it was treated with or contained a pesticide not to protect the article or substance itself, but to protect the user, and that the product was therefore not exempt from registration requirements under the circumstances set forth at 40 C.F.R Section 152.25(a).
20. Section 14(a) of FIFRA, 7 U.S.C. § 136l(a), in conjunction with the Debt Collection Improvement Act of 1996, authorizes the assessment of a civil penalty.
21. Section 14(a)(4) of FIFRA, 7 U.S.C. § 136l(a)(4), requires EPA to consider the appropriateness of the assessed penalty to the size of business of the Respondent, the effect on Respondent's ability to continue in business, and the gravity of the alleged violation.
22. After consideration of the factors set forth in Section 14(a)(4) of FIFRA, 7 U.S.C. § 136l(a)(4), the EPA proposes to assess a total civil penalty of FORTY THOUSAND NINE HUNDRED FIFTY DOLLARS (\$40,950) against the Respondent for the above-described alleged violations. Civil penalties under Section 14(a) of FIFRA, 7 U.S.C. § 136l(a), may be assessed by Administrative Order.

### III. Consent Agreement

23. For the purposes of this CAFO, Respondent admits the jurisdictional allegations set forth above and neither admits nor denies, and shall not be deemed to admit or deny the factual and legal allegations. Respondent hereby specifically reserves, does not waive its right to

dispute, and does not admit or deny such factual and legal allegations for purposes of any judicial, administrative or other proceedings regarding this matter, whether involving EPA or any other party.

24. Respondent waives its right to a hearing on the allegations contained herein and its right to appeal the proposed final order accompanying the consent agreement.
25. Without any admission of liability in connection with this matter, Respondent consents to pay the amount of the penalty proposed by EPA in settlement of this matter as set forth in this CAFO.
26. Respondent certifies that as of the date of its execution of this CAFO, it is in compliance with all relevant requirements of FIFRA to the best of its knowledge, information and belief.
27. Compliance with this CAFO shall resolve the allegations of the violations contained herein. This CAFO shall not otherwise affect any liability of Respondent to the United States. Other than as expressed herein, neither EPA nor Complainant waives any right to bring an enforcement action against Respondent for violation of any federal or state statute, regulation or permit, to initiate an action for imminent and substantial endangerment, or to pursue criminal enforcement.
28. Complainant and Respondent agree to settle this matter by their execution of this CAFO. The parties agree that the settlement of this matter is in the public interest and that this CAFO is consistent with the applicable requirements of FIFRA.

IV. Final Order

29. **Respondent is assessed a civil penalty of FORTY THOUSAND NINE HUNDRED FIFTY DOLLARS (\$40,950) which shall be paid within 30 days from the effective date of this CAFO.**
30. Respondent shall remit the penalty by either a cashier's, or certified check made payable to the "Treasurer, United States of America," and shall send the check via U.S. mail to the following address:

US Environmental Protection Agency  
Fines and Penalties  
Cincinnati Finance Center  
PO Box 979077  
St. Louis, MO 63197-9000.

**The check shall reference the name and the Docket Number of the CAFO  
[“Schering-Plough Healthcare Products, Inc., FIFRA-04-2007-3027(b)”].**

31. At the time of payment, Respondent shall send a separate copy of the check and a written statement that the payment is being made in accordance with this CAFO, to the following persons at the following addresses:

Regional Hearing Clerk  
U.S. EPA - Region 4  
61 Forsyth Street, S.W.  
Atlanta, Georgia 30303-8960;

Melba Table  
Pesticides Management Section  
U.S. EPA - Region 4  
61 Forsyth Street  
Atlanta, Georgia 30303-8960;



and

Saundi Wilson  
Office of Environmental Accountability  
U.S. EPA - Region 4  
61 Forsyth Street  
Atlanta, Georgia 30303-8960.

32. For the purposes of state and federal income taxation, Respondent shall not be entitled, and agrees not to attempt, to claim a deduction for any civil penalty payment made pursuant to this CAFO. Any attempt by Respondent to deduct any such payments shall constitute a violation of this CAFO.
33. Pursuant to 31 U.S.C. § 3717, EPA is entitled to assess interest and penalties on debts owed to the United States and a charge to cover the cost of processing and handling a delinquent claim. Interest will therefore begin to accrue on the civil penalty payment provided for under the CAFO from the date of entry of this CAFO, if the penalty is not paid by the date required. A charge will also be assessed to cover the administrative costs, both direct and indirect, of overdue debts. In addition, a late payment penalty charge shall be applied on any principle amount not paid within 90 days of the due date.
34. Complainant and Respondent shall bear their own costs and attorney fees in this matter.
35. This CAFO shall be binding upon the Respondent, its successors and assigns.
36. The undersigned representative of the party to this CAFO certifies that he or she is fully authorized by the party represented to enter into this CAFO and legally binds that party to this CAFO.

V. Effective Date

37. The effective date of this CAFO shall be the date on which the CAFO is filed with the Regional Hearing Clerk.

**AGREED AND CONSENTED TO:**

**Schering-Plough HealthCare Products, Inc.**

By: [Signature] (Signature)  
Name: Brent Saunders (Typed or Printed)  
Title: President (Typed or Printed)

Date: 7/23/07



**U.S. Environmental Protection Agency**

[Signature]  
By: Beverly H. Banister  
Director  
Air, Pesticides and Toxics  
Management Division  
61 Forsyth Street  
Atlanta, Georgia 30303-8960

Date: 10/4/07

**APPROVED AND SO ORDERED** this 9<sup>th</sup> day of October 2007.

[Signature]  
Susan B. Schub  
Regional Judicial Officer

CERTIFICATE OF SERVICE

I hereby certify that I have this day served a true and correct copy of the foregoing Consent Agreement and Final Order, in the Matter of: Schering-Plough Healthcare Products, Inc., FIFRA Docket No. 04-2007-3027(b), on the parties listed below in the manner indicated.

For Complainant:

Melba Table

(Via EPA's internal mail)

U.S. EPA - Region 4, 4APT-PTSB

Pesticides Management Section

61 Forsyth Street

Atlanta, GA 30303-8960

Nancy Tommelleo

(Via EPA's internal mail)

Office of Environmental Accountability

U.S. EPA - Region 4

61 Forsyth Street

Atlanta, GA 30303-8960

For Respondent:

Cathy Trinkle

(Via Certified Mail - Return Receipt Requested)

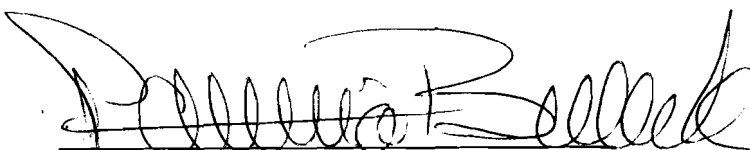
Schering-Plough Corporation

2000 Galloping Hill Road

Kenilworth, NJ 07033

Date:

10-9-07



Regional Hearing Clerk

United States Environmental

Protection Agency, Region 4

Sam Nunn Atlanta Federal Center

61 Forsyth Street

Atlanta, GA 30303-8960

(404) 562-9511

**EPA ACCOUNTS RECEIVABLE CONTROL NUMBER FORM**

**TO BE COMPLETED BY THE ORIGINATING OFFICE:**

(Attach a copy of the final order and transmittal letter to Defendant/Respondent)

This form was originated by: Saundi J Wilson on 10/4/07  
(Name) (Date)

in the OEA at (404) 562-9504  
(Office) (Telephone Number)

Non-SF Judicial Order/Consent Decree  
USAO COLLECTS

Administrative Order/Consent Agreement  
FMO COLLECTS PAYMENT

SF Judicial Order/Consent Decree  
DOJ COLLECTS

Oversight Billing - Cost Package required:  
Sent with bill

Not sent with bill

Other Receivable

Oversight Billing - Cost Package not required

This is an original debt

This is a modification

PAYEE: Schering-Plough Healthcare Products  
(Name of person and/or Company/Municipality making the payment)

The Total Dollar Amount of the Receivable: \$ 40,950  
(If installments, attach schedule of amounts and respective due dates. See Other side of this form.)

The Case Docket Number: FIFRA 04-2007-3627(b)

The Site Specific Superfund Account Number: \_\_\_\_\_

The Designated Regional/Headquarters Program Office: \_\_\_\_\_

**TO BE COMPLETED BY LOCAL FINANCIAL MANAGEMENT OFFICE:**

The IFMS Accounts Receivable Control Number is: \_\_\_\_\_ Date \_\_\_\_\_

If you have any questions, please call: \_\_\_\_\_ of the Financial Management Section at: \_\_\_\_\_

**DISTRIBUTION:**

A. **JUDICIAL ORDERS:** Copies of this form with an attached copy of the front page of the **FINAL JUDICIAL ORDER** should be mailed to:

- |  |                              |
|--|------------------------------|
| 1. Debt Tracking Officer<br>Environmental Enforcement Section<br>Department of Justice RM 1647<br>P.O. Box 7611, Benjamin Franklin Station<br>Washington, D.C. 20044 | 2. Originating Office (EAD)  |
|  | 3. Designated Program Office |

B. **ADMINISTRATIVE ORDERS:** Copies of this form with an attached copy of the front page of the Administrative Order should be to:

- |                           |                              |
|---------------------------|------------------------------|
| 1. Originating Office     | 3. Designated Program Office |
| 2. Regional Hearing Clerk | 4. Regional Counsel (EAD)    |