

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2

U.S. ENVIRONMENTAL
PROTECTION AGENCY-REG. II
2008 JAN -3 PM 2: 08
REGIONAL HEARING
CLERK

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: :
In the Matter of : :
: : **COMPLAINT AND NOTICE OF**
MOVA PHARMACEUTICAL CORPORATION : **OPPORTUNITY FOR HEARING**
: :
Respondent. : :
: : Docket No. EPCRA-02-2008-4301
: :
Proceeding under Section 325(c) : :
of Title III of the Superfund : :
Amendments and Reauthorization Act. : :
: :
-----X

COMPLAINT

Complainant, as and for her Complaint against Respondent, hereby alleges:

1. This civil administrative action is instituted pursuant to Section 325(c) of Title III of the Superfund Amendments and Reauthorization Act (42 U.S.C. §11001 *et seq.*) which is also known as the Emergency Planning and Community Right-to-Know Act of 1986 (hereinafter, "EPCRA").
2. The Complainant, Dore LaPosta, Director, Division of Enforcement and Compliance Assistance, United States Environmental Protection Agency ("EPA"), Region 2, has been duly delegated the authority to institute this action.
3. Respondent is Mova Pharmaceutical Corporation.
4. Respondent maintains a facility that is the subject of this Complaint at State RD 670 KM 2.7, Manati, Puerto Rico 00674 (hereinafter, "Respondent's facility").
5. Pursuant to Sections 313 and 328 of EPCRA, 42 U.S.C. §§11023 and 11048, respectively, EPA promulgated the Toxic Chemical Release Reporting: Community Right-to-Know Rule (40 C.F.R. Part 372).

6. Under Section 313 of EPCRA and 40 C.F.R. §372.22, owners or operators of a facility subject to the requirements of Section 313(b) are required to submit annually, no later than July 1 of each year, a Toxic Chemical Release Inventory Reporting Form R report, EPA Form 9350-1 (hereinafter, "Form R report"), for each toxic chemical listed under 40 C.F.R. §372.65 and/or 40 C.F.R. §372.28 that was manufactured, imported, processed, or otherwise used during the preceding calendar year in quantities exceeding the established toxic chemical thresholds. The completed and correct Form R report is required to be submitted to the Regional Administrator of the EPA and to the State in which the subject facility is located.

7. As an alternative to the requirements set forth in paragraph "6" above, pursuant to Section 313(f)(2) of EPCRA (42 U.S.C. §11023(f)(2)), and 40 C.F.R. §372.27, owners or operators of a facility subject to the requirements of Section 313(b), with respect to the manufacture, process or otherwise use of a toxic chemical, may apply an alternate threshold of one million (1,000,000) pounds per year to that chemical if the conditions set forth in 40 C.F.R. §372.27(a) are met. Pursuant to 40 C.F.R. §372.27(b), if the aforementioned alternate threshold for a specific toxic chemical is applicable, such owners or operators, in lieu of filing a Form R report therefore, may submit "EPA Toxic Chemical Release Inventory Form A" (EPA Form 9350-2) (formerly the "Certification Statement"; see 59 Fed. Reg. 61488; November 30, 1994). EPA has excluded Persistent Bioaccumulative Toxic Chemicals (PBTs) from eligibility for the "Alternate Threshold for facilities with Low Annual Reportable Amounts." (40 C.F.R. §372.27(e))

8. This Complaint serves notice that Complainant has reason to believe that Respondent failed to submit timely, complete and correct Toxic Chemical Release Inventory Reporting Form R or Form A reports as required by Section 313 of EPCRA (42 U.S.C. §11023), and the Federal regulations that set out in greater detail the Section 313 reporting requirements codified at 40 C.F.R. Part 372.

9. Respondent is a "person" within the meaning of Section 329(7) of EPCRA (42 U.S.C. §11049(7)).

10. Respondent is an owner of a "facility" as that term is defined by Section 329(4) of EPCRA (42 U.S.C. §11049(4)), and by 40 C.F.R. §372.3.

11. Respondent is an operator of a "facility" as that term is defined by Section 329(4) of EPCRA (42 U.S.C. §11049(4)), and by 40 C.F.R. §372.3.

12. Respondent's facility has 10 or more "full time employees" as that term is defined by 40 C.F.R. §372.3.

13. Respondent's facility is in the North American Industry Classification System (NAICS) Code 325412 and Standard Industrial Classification Code 2834.

14. Respondent's facility is subject to the requirements of EPCRA, Section 313(b) (42 U.S.C. §11023(b)), and 40 C.F.R. §372.22.

15. On or about July 2, 2007, Mova Pharmaceutical Corporation sent a letter to the United States Environmental Protection Agency - Region 2 in which the company voluntarily disclosed the failure to submit a Toxic Release Inventory Form R report to the EPA for dichloromethane (a.k.a. methylene chloride) for calendar year 2005 under Section 313 of EPCRA and for underestimating releases and transfers for methanol for calendar year 2005.

COUNT 1

16. Complainant realleges each allegation contained in Paragraphs "1" through "15" with the same force and effect as if fully set forth herein.

17. Respondent otherwise used (as defined in 40 C.F.R. §372.3) approximately 59,248 pounds of dichloromethane in calendar year 2005.

18. Dichloromethane (Chemical Abstract Service No. 75-09-02) is listed under 40 C.F.R. §372.65 as an EPCRA Section 313 chemical for which reporting is required.

19. The established threshold amount for otherwise using dichloromethane for the 2005 calendar year was 10,000 pounds. [40 C.F.R. §372.25]

20. Respondent was required to submit by July 1, 2006 a complete and correct Form R report for dichloromethane for the calendar year 2005 to the Administrator of EPA and to the Commonwealth of Puerto Rico.

21. Respondent voluntarily submitted the Form R report for dichloromethane for the calendar year 2005 on October 11, 2007, the postmark date. The Form R report was greater than one year late.

22. Respondent failed to submit to the Administrator and to the Commonwealth of Puerto Rico, in a timely manner, a complete and correct Form R report for dichloromethane for the calendar year 2005.

23. Respondent's failure to submit in a timely manner a complete and correct Form R report for the above-described toxic chemical constitutes a failure or refusal to comply with Section 313 of EPCRA (42 U.S.C. §11023), and with 40 C.F.R. §372.30.

COUNT 2

24. Complainant realleges each allegation contained in Paragraphs "1" through "15" with the same force and effect as if fully set forth herein.

25. This complaint serves notice that Complainant has reason to believe that Respondent failed to estimate reasonably the annual quantity of methanol transferred or released to an environmental medium on its Form R as required by Section 313 of EPCRA, 42 U.S.C. 11023, and the Federal regulations that set out in greater detail the Section 313 reporting requirements, 40 C.F.R. Part 372.

26. Methanol is listed under 40 C.F.R. Part 372.65.

27. Respondent under reported the quantity of methanol transferred to an off-site location in Section 6.1.2 of the Form R for calendar year 2005 by approximately 45.8%. Respondent reported 38,725 pounds of methanol as transferred off-site on its Form R report for calendar year 2005. This estimate was revised to 71,404 pounds on October 11, 2007.

28. Respondent under reported the quantity of methanol as an on-site disposal or other releases in Section 8.1b of the Form R for calendar year 2005 by approximately 29.8%. Respondent reported 774 pounds of methanol as an on-site disposal or release on its Form R report for calendar 2005. This estimate was revised to 1,102 pounds on October 11, 2007.

29. Respondent under reported the quantity of methanol treated off-site in Section 8.7 of the Form R for calendar year 2005 by approximately 45.8%. Respondent reported 38,725 pounds of methanol treated off-site on its Form R report for calendar 2005. This estimate was revised to 71,404 pounds on October 11, 2007.

30. Respondent was required to report a reasonable estimate of its annual releases and transfers of methanol in Sections 6 and 8 on its Form R for the 2005 calendar year.

31. Respondent's failure to report reasonable estimates of its annual releases and transfers of the above-mentioned toxic chemical on its Form R for the 2005 calendar year constitutes a failure or refusal to comply with Section 313 of EPCRA, 42 U.S.C. § 11023, and with 40 C.F.R. § § 372.30 and 372.85.

PROPOSED CIVIL PENALTY

The proposed civil penalty has been determined in accordance with Section 325(c) of EPCRA (42 U.S.C. §11045(c)), which authorizes the assessment of a civil penalty of up to \$25,000 per day for each violation of Section 313 of EPCRA 42 U.S.C. §11023. As per the Civil Monetary Penalty Inflation Adjustment Final Rule dated December 31, 1996, effective January 30, 1997, any violation may be assessed up to \$27,500 for each violation after that effective date [61 Fed. Reg. 69359 (1996)].

To develop the proposed penalty in this Complaint, Complainant has taken into account the particular facts and circumstances of this case, to the extent known at the time, with specific reference to EPA's "Enforcement Response Policy for Section 313 of EPCRA" dated August 10, 1992, a copy of which is available upon request. This policy provides a rational, consistent and equitable calculation methodology for penalties in particular cases. In calculating a proposed penalty pursuant to this policy, EPA takes into account the gravity of the violations, as well as certain factors such as a violator's history of prior such violations and its ability to pay.

The Complainant proposes, subject to receipt and evaluation of further relevant information, that Respondent be assessed the following civil penalties for the violations alleged in the Complaint:

COUNT 1 - Failure to submit a Toxic Chemical Release Inventory Reporting Form R report for dichloromethane for calendar year 2005 in a timely manner.	\$ 21,922
COUNT 2 - Data Quality Errors on the 2005 Form R for methanol	\$ 12,895
	<u>\$34,817</u>
*TOTAL PROPOSED PENALTY (ROUNDED):	\$ 34,800

*In accordance with Agency policies regarding modifications to the relevant penalty policies, the total gravity-based penalty amount is rounded to the nearest unit of 100 dollars.

PROCEDURES GOVERNING THIS ADMINISTRATIVE LITIGATION

The rules of procedure governing this civil administrative litigation have been set forth in 64 Fed. Reg: 40138 (July 23, 1999), entitled, "Consolidated Rules of Practice Governing the Administrative Assessments of Civil Penalties, Etc.", and which are to be codified at 40 C.F.R. Part 22. A copy of these rules accompanies this "Complaint, Compliance Order and Notice of Opportunity for Hearing" (hereinafter referred to as the "Complaint").

A. Answering The Complaint

Where Respondent intends to contest any material fact upon which the Complaint is based, to contend that the proposed penalty is inappropriate or to contend that Respondent is entitled to judgment as a matter of law, Respondent must file with the Regional Hearing Clerk of EPA, Region 2, both an original and one copy of a written Answer to the Complaint. 40 C.F.R. §22.15(a). While that provision requires that an Answer must be filed within 30 days after service of a Complaint, EPA, Region 2, has administratively extended the deadline for such filing in this proceeding, and Respondent's Answer accordingly must be filed within 90 days of service of the Complaint. The address of the Regional Hearing Clerk of EPA, Region 2, is:

Ms. Karen Maples, Regional Hearing Clerk
Office of the Regional Hearing Clerk
U.S. Environmental Protection Agency -Region 2
290 Broadway, 16th Floor (1631)
New York, New York 10007-1866

Respondent shall also then serve one copy of the Answer to the Complaint upon Complainant and any other party to the action. [40 C.F.R. §22.15(a)]

Respondent's Answer to the Complaint must clearly and directly admit, deny, or explain each of the factual allegations that are contained in the Complaint and with regard to which Respondent has any knowledge. 40 C.F.R. §22.15(b). Where Respondent lacks knowledge of a particular factual allegation and so states in its Answer, the allegation is deemed denied. [40 C.F.R. §22.15(b)] The Answer shall also set forth: (1) the circumstances or arguments that are alleged to constitute the grounds of defense, (2) the facts that Respondent disputes (and thus intends to place at issue in the proceeding) and (3) whether Respondent requests a hearing. [40 C.F.R. §22.15(b)]

Respondent's failure affirmatively to raise in the Answer facts that constitute or that might constitute the grounds of its defense may preclude Respondent, at a subsequent stage in this proceeding, from raising such facts and/or from having such facts admitted into evidence at a hearing.

B. Opportunity To Request A Hearing

If requested by Respondent in its answer, a hearing upon the issues raised by the Complaint and Answer may be held. 40 C.F.R. §22.15(c). If, however, Respondent does not request a hearing, the Presiding Officer (as defined in 40 C.F.R. §22.3) may hold a hearing if the Answer raises issues appropriate for adjudication. [40 C.F.R. §22.15(c)]

Any hearing in this proceeding will be held at a location determined in accordance with 40 C.F.R. §22.21(d). A hearing of this matter will be conducted in accordance with the applicable provisions of the Administrative Procedure Act (5 U.S.C. §§551-59), and the procedures set forth in Subpart D of 40 C.F.R. Part 22.

C. Failure To Answer

If Respondent fails in its Answer to admit, deny, or explain any material factual allegation contained in the Complaint, such failure constitutes an admission of the allegation. [40 C.F.R. §22.15(d)] If Respondent fails to file a timely Answer to the Complaint [i.e. in accordance with the period set forth in 40 C.F.R. §22.15(a); extended to 90 days for this Complaint], Respondent may be found in default upon motion. [40 C.F.R. §22.17(a)] Default by Respondent constitutes, for purposes of the pending proceeding only, an admission of all facts alleged in the Complaint and a waiver of Respondent's right to contest such factual allegations. [40 C.F.R. §22.17(a)] Following a default by Respondent for a failure to timely file an Answer to the Complaint, any order issued therefor shall be issued pursuant to 40 C.F.R. §22.17(c).

Any penalty assessed in the default order shall become due and payable by Respondent without further proceedings 30 days after the default order becomes final pursuant to 40 C.F.R. §22.27(c). [40 C.F.R. §22.17(d)] If necessary, EPA may then seek to enforce such Final Order of default against Respondent, and to collect the assessed penalty amount, in federal court.

D. Exhaustion Of Administrative Remedies

Where Respondent fails to appeal an adverse initial decision to the Environmental Appeals Board pursuant to 40 C.F.R. §22.30, and that initial decision thereby becomes a Final Order pursuant to the terms of 40 C.F.R. §22.27(c), Respondent waives its right to judicial review. [40 C.F.R. §22.27(d)]

In order to appeal an initial decision to the Agency's Environmental Appeals Board [EAB; see 40 C.F.R. §1.25(e)], Respondent must do so "within thirty (30) days after the initial decision is served." Pursuant to 40 C.F.R. §22.07(c), where service is effected by mail, "five days shall be added to the time allowed by these rules for the filing of a responsive pleading or document". Note that the 45-day period provided for in 40 C.F.R. §22.27(c) [discussing when an initial decision becomes a Final Order] does not pertain to or extend the time period prescribed in 40 C.F.R. §22.30(a) for a party to file an appeal to the EAB of an adverse initial decision.

INFORMAL SETTLEMENT CONFERENCE

Whether or not Respondent requests a formal hearing, EPA encourages settlement of this proceeding consistent with the provisions of the Act and its applicable regulations. [40 C.F.R. §22.18(b)] At an informal conference with a representative(s) of Complainant, Respondent may comment on the charges made in this Complaint, and Respondent may also provide whatever additional information that it believes is relevant to the disposition of this matter, including: (1) actions Respondent has taken to correct any or all of the violations herein alleged, (2) any information relevant to Complainant's calculation of the proposed penalty, (3) the effect the proposed penalty would have on Respondent's ability to continue in business and/or (4) any other special facts or circumstances Respondent wishes to raise.

Complainant has the authority to modify the amount of the proposed penalty, where appropriate, to reflect any settlement agreement reached with Respondent, to reflect any relevant information previously not known to Complainant or to dismiss any or all of the charges, if Respondent can demonstrate that the relevant allegations are without merit and that no cause of action as herein alleged exists. Respondent is referred to 40 C.F.R. §22.18.

Any request for an informal conference or any questions that Respondent may have regarding this Complaint should be directed to:

Ms. Mary Ann Kowalski, MS, MPH
R2 TRI Program Enforcement Coordinator
United States Environmental Protection Agency - Region 2
Pesticides and Toxic Substances Branch
2890 Woodbridge Avenue, Bldg. 10, (MS-105)
Edison, New Jersey 08837

Phone: (732) 906-6815, Email: kowalski.mary@epa.gov

The parties may engage in settlement discussions irrespective of whether Respondent has requested a hearing. [40 C.F.R. §22.18(b)(1)] Respondent's requesting a formal hearing does not prevent it from also requesting an informal settlement conference; the informal conference procedure may be pursued simultaneously with the formal adjudicatory hearing procedure. A

request for an informal settlement conference constitutes neither an admission nor a denial of any of the matters alleged in the Complaint. Complainant does not deem a request for an informal settlement conference as a request for a hearing as specified in 40 C.F.R. §22.15(c). A request for an informal settlement conference does not affect Respondent's obligation to file a timely Answer to the Complaint pursuant to 40 C.F.R. §22.15. No penalty reduction, however, will be made simply because an informal settlement conference is held.

Any settlement that may be reached as a result of an informal settlement conference shall be embodied in a written Consent Agreement. [40 C.F.R. §22.18(b)(2)] In accepting the Consent Agreement, Respondent waives its right to contest the allegations in the Complaint and waives its right to appeal the Final Order that is to accompany the Consent Agreement. [40 C.F.R. §22.18(b)(2)] In order to conclude the proceeding, a Final Order ratifying the parties' agreement to settle will be executed. [40 C.F.R. §22.18(b)(3)]

Respondent's entering into a settlement through the signing of such Consent Agreement and its complying with the terms and conditions set forth in the such Consent Agreement terminate this administrative litigation and the civil proceedings arising out of the allegations made in the Complaint. Respondent's entering into a settlement does not extinguish, waive, satisfy or otherwise affect its obligation and responsibility to comply with all applicable statutory and regulatory requirements, and to maintain such compliance.

RESOLUTION OF THIS PROCEEDING WITHOUT HEARING OR CONFERENCE

Instead of filing an Answer, Respondent may resolve this proceeding by paying the specific penalty proposed in the Complaint and filing a copy of the check or other instrument of payment with the Regional Hearing Clerk, Region 2 (at the New York address noted above) 40 C.F.R. §22.18(a). A copy of the check or other instrument of payment should also be provided to the EPA contact identified on the previous page.

Such payment shall be made by cashier's or certified check or by Electronic Fund Transfer (EFT). If the payment is made by check, then the check shall be made payable to the "Treasurer, United States of America," and shall be mailed to :

U.S. Environmental Protection Agency
Fines and Penalties
Cincinnati Finance Center
P.O. Box 979077
St. Louis, MO 63197-9000

The check shall be identified with a notation thereon listing the following:
IN THE MATTER OF MOVA PHARMACEUTICAL CORPORATION, and shall bear thereon the Docket Number: EPCRA-02-2008-4301.

If Respondent chooses to make the payment by EFT, then Respondent shall provide the following information to its remitter bank:

- 1) Amount of Payment
- 2) SWIFT address: FRNYUS33, 33 Liberty Street, New York, NY 10045.
- 3) Account Code for Federal Reserve Bank of New York receiving payment: 6801072
- 4) Federal Reserve Bank of New York ABA routing number: 021030004.
- 5) Field Tag 4200 of the Fedwire message should read:
" D 68010727 Environmental Protection Agency."
- 6) Name of Respondent: **Mova Pharmaceutical Corporation**
- 7) Case Number: **EPCRA-02-2008-4301**

Whether the payment is made by check or by EFT, the Respondent shall promptly thereafter furnish reasonable proof that such payment has been made, to both:

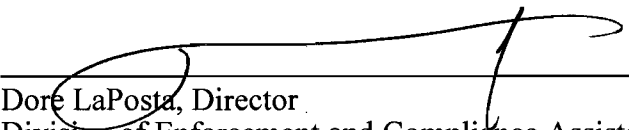
Ms. Mary Ann Kowalski. MS, MPH
Environmental Protection Agency, Region 2
Pesticides and Toxic Substances Branch
2890 Woodbridge Avenue (MS-105)
Edison, New Jersey 08837

and

Karen Maples, Regional Hearing Clerk
Environmental Protection Agency, Region 2
290 Broadway, 16th floor
New York, New York 10007-1866.

The civil penalty constitutes a penalty within the meaning of 26 U.S.C. § 162(f). Pursuant to 40 C.F.R. §22.18(a)(3), upon EPA's receipt of such payment, the Regional Administrator of EPA, Region 2 (or, if designated, the Regional Judicial Officer), shall issue a Final Order. Issuance of this Final Order terminates this administrative litigation and the civil proceedings arising out of the allegations made in the Complaint. Further, pursuant to 40 C.F.R. §22.18(a)(3), the making of such payment by Respondent shall constitute a waiver of Respondent's right both to contest the allegations made in the Complaint and to appeal said Final Order to federal court. Such payment does not extinguish, waive, satisfy or otherwise affect Respondent's obligation and responsibility to comply with all applicable regulations and requirements, and to maintain such compliance.

Dated: DECEMBER 21, 2007


Doré LaPosta, Director
Division of Enforcement and Compliance Assistance
United States Environmental Protection Agency - Region 2
290 Broadway
New York, New York 10007

To: Ileana Quiñones, Vice President Manatí Operations
Mova Pharmaceutical Corporation
P.O. Box 31199
Manatí, Puerto Rico 00674

Enclosures

cc. Carlos W. Lopez Freytes, Chairman
Puerto Rico State Emergency Response Commission
P.O. Box 11488
Santurce, Puerto Rico 00910-1488

CERTIFICATE OF SERVICE

This is to certify that I have this day caused to be mailed a copy of the foregoing Complaint, bearing Docket Number EPCRA -02-2008-4301, and a copy of the Consolidated Rules of Practice, 40 C.F.R. Part 22 (64 Federal Register 40176 [July 23, 1999]), by Certified Mail, Return Receipt Requested, to Mr. Ileana Quiñones, Vice President Manati Operations, Mova Pharmaceutical Corporation. I mailed the original and one copy of the foregoing Complaint to the Office of the Regional Hearing Clerk, United States Environmental Protection Agency, Region 2.

Dated:

January 3, 2008



Mary Ann Kowalski, MS, MPH
Pesticides and Toxic Substances Branch
United States Environmental Protection Agency
2890 Woodbridge Avenue (MS-105)
Edison, New Jersey 08837