

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region 2**

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In the Matter of	:	<u>CONSENT AGREEMENT AND</u>
	:	<u>FINAL ORDER</u>
Merial (IA) LLP,	:	
	:	
Respondent.	:	
	:	Docket No.
Proceeding under The Federal	:	<u>FIFRA-02-2011-5302</u>
Insecticide, Fungicide and	:	
Rodenticide Act, as amended.	:	
-----X	:	

U.S. ENVIRONMENTAL PROTECTION AGENCY
 2011 SEP 20 A 6:58 PM

This administrative proceeding for the assessment of a civil penalty is being commenced pursuant to Section 14(a) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 U.S.C. § 136l(a) (“FIFRA” or the “Act”). Pursuant to Section 22.13 of the revised Consolidated Rules of Practice, Title 40 of the Code of Federal Regulations (“C.F.R.”), 40 C.F.R. § 22.13(b) (64 Fed. Reg. 40181, July 23, 1999), where parties agree to settlement of one or more causes of action before the filing of a Complaint, a proceeding may simultaneously be commenced and concluded by the issuance of a Consent Agreement and Final Order (“CA/FO”) pursuant to 40 C.F.R. §§ 22.18(b)(2) and (3). This administrative proceeding constitutes one that is simultaneously being commenced and concluded pursuant to said provisions of 40 C.F.R. § 22.18(b).

It has been agreed by the parties that settling this matter by entering into this CA/FO pursuant to 40 C.F.R. §§ 22.13(b) and 22.18(b)(2) and (3) is an appropriate means of resolving specified claims against Respondent without further litigation. To that end, the parties have periodically held settlement discussions. This CA/FO is being issued pursuant to said provisions of 40 C.F.R. Part 22. No findings of fact or conclusions of law have been judicially or administratively made, and no admissions have been made by Respondent. The following constitute EPA’s findings of fact and conclusions of law based on information of which Complainant was aware as of June 1, 2011.

EPA FINDINGS OF FACT

1. Respondent is Merial (IA) LLP (“Respondent” or “Merial”), a limited liability partnership organized, existing since 1997 and doing business under and by virtue of the laws of the Commonwealth of Puerto Rico, with its principal place of business located in San Juan, Puerto Rico.

2. Merial is a subsidiary of, and controlled by, Merial Limited, a company limited by shares registered in England and Wales (Reg. No. 3332751) with registered offices at P.O. Box 327, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5QA, England, and domesticated in the State of Delaware as Merial LLC with a place of business at 3239 Satellite Boulevard, Duluth, Georgia 30096.

3. Respondent conducts business operations at a facility in the Pepsi Industrial Park, the registered address of which is Carrera # 2 KM 9.5, Toa Baja, Puerto Rico 00959.

4. Respondent is in the business of distributing into foreign and interstate commerce through importations into and/or exportations from the United States and through admissions into a U.S. foreign-trade zone in Puerto Rico and withdrawals from the foreign-trade zone for exportation only animal health care products and pharmaceuticals for farm and companion animals. United States foreign-trade zones are limited access sites designated by the United States Foreign-Trade Zone's Board and administered by the United States Customs and Border Protection ("CBP"), and such zones are located within the physical boundary of the United States but not within the Customs territory of the United States.

5. On or about May 30, 2002, Respondent and Jose G. Flores, Inc. ("Flores"), entered into a contractual agreement, denominated "CUSTOMS POWER OF ATTORNEY/DESIGNATION AS EXPORT FORWARDING AGENT," pursuant to which Respondent "constitute[d] and appoint[ed]" Flores "to act for and on [Merial's] behalf as a true and lawful agent and attorney" in accordance with the terms and conditions set forth in said contract, one of which stipulated that Respondent authorized Flores to act within the United States as the forwarding agent for export transactions.

6. On each of the following dates, Respondent, through its contract with Flores, admitted into the Puerto Rico foreign-trade zone on a filed CBPF 214 with Zone-Restricted status (*i.e.* under Customs bond and supervision requiring shipments for export only authorization by CBP) a product known as "Frontline Plus," bearing labeling in Spanish, into the United States (*i.e.* Puerto Rico):

- a) December 11, 2008;
- b) December 17, 2008;
- c) February 19, 2009;
- d) April 1, 2009; and
- e) June 5, 2009.

7. Frontline Plus is a pesticide that is intended as monthly topical flea and tick preventative for dogs and cats, and it kills fleas and ticks, including the brown dog tick, the American dog tick and the deer tick. Frontline Plus is registered with the EPA in accordance with the requirements of, and pursuant to the procedures set forth in, Section 3 of FIFRA, 7 U.S.C. § 136(a).

8. Through the Puerto Rico foreign-trade zone no. 7 operated by Flores, Respondent exported from the United States foreign-trade zone the Frontline Plus to the following countries on the dates listed below:

- a) Costa Rica on or about each of the following four dates: March 27, 2009; May 22, 2009; June 19, 2009; and July 31, 2009.
- b) Guatemala on or about each of the following three dates: April 3, 2009; May 22, 2009; and June 26, 2009.
- c) Honduras on or about each of the following four dates: April 3, 2009; May 22, 2009; June 19, 2009; and June 26, 2009.
- d) Nicaragua on or about each of the following two dates: April 21, 2009; and July 10, 2009.
- e) Panama on or about each of the following four dates: March 20, 2009; April 30, 2009; June 5, 2009; and June 19, 2009.
- f) Dominican Republic on or about May 15, 2009.
- g) El Salvador on or about each of the following three dates: March 20, 2009; May 22, 2009; and June 26, 2009.

9. For each of the aforementioned (§ 6, above) foreign-trade zone admissions of Frontline Plus, Respondent had not filed (nor had Flores) with EPA a “Notice of Arrival of Pesticides and Devices,” EPA Form 3540–1, pursuant to 19 C.F.R. § 12.112(a), prior to the arrival of the shipment in the United States foreign-trade zone (hereinafter said notice referred to as a “Notice of Arrival”).

10. At no time prior to July 28, 2009 (if not later) was the aforementioned (§ 6, above) Frontline Plus ever registered for use and sale in the United States in its condition as admitted into the foreign-trade zone, *i.e.* with Spanish labeling and without a “Not Registered for Use in the United States of America” statement, in accordance with the requirements of, and pursuant to the procedures set forth in, Section 3 of FIFRA, 7 U.S.C. § 136(a).

11. For each of the aforementioned (§ 8, above) foreign-trade zone exportations, Respondent had never submitted (nor had Flores) to EPA a “statement that indicates the foreign purchaser understands that the product is not registered for use in the United States and cannot be sold in the United States” pursuant to 40 C.F.R. § 168.75(c)(1)(v) (hereinafter said statement referred to as the “Foreign Purchaser Acknowledgment statement”).

12. For each of the aforementioned (§ 8, above) foreign-trade zone exportations, Respondent failed to include on the label of the packaging holding the Frontline Plus in a

conspicuous manner the words, “Not Registered for Use in the United States of America.”

13. As a consequence of its failure to include the words, “Not Registered for Use in the United States of America,” for each of the aforementioned (¶ 8, above) exportations, Respondent distributed a pesticide that was misbranded.

EPA CONCLUSIONS OF LAW

1. Since its formation in 1997, Respondent has been, and continues to be, a “person” (as defined by Section 2(s) of FIFRA, 7 U.S.C. § 136(s)).

2. Puerto Rico is a “state” within the meaning of Section 2(aa) of FIFRA, 7 U.S.C. § 136(aa).

3. Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N), makes it “unlawful for any person *** who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by” subchapter II of FIFRA, 7 U.S.C. §§ 136 - 136y.

4. Pursuant to 19 C.F.R. § 12.112(a), a regulation promulgated pursuant to and under the authority of Section 17 of FIFRA, 7 U.S.C. § 136o, “[a]n importer desiring to import pesticides ...into the United States shall submit to the Administrator” of EPA a Notice of Arrival of Pesticides “prior to the arrival of the shipment in the United States.”

5. For each of the aforementioned (¶ 6, above) foreign-trade zone admissions of Frontline Plus, Respondent was the “importer desiring to import pesticides” into the United States within the meaning of 19 C.F.R. § 12.112(a).

6. Each of the aforementioned (¶ 9 of the “EPA Findings of Fact,” above) failures to file constitutes an act prohibited by, and thus a violation of, 19 C.F.R. § 12.112(a), as a consequence of which each such failure constitutes an act made unlawful by, and thus a violation of, Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N).

7. Section 17(a)(2) of FIFRA, 7 U.S.C. § 136o(a)(2), provides, in part, that “no pesticide...intended solely for export to any foreign country shall be deemed in violation of this subchapter *** in the case of any pesticide other than a pesticide registered under section 136a ...if, prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under this subchapter.”

8. Pursuant to 40 C.F.R. § 168.75(c), “[a]n exporter of an unregistered pesticidal product must submit a purchaser acknowledgment statement to EPA containing the information stated in paragraph (c)(1) of this section,” and the information contained therein includes “[a] statement that indicates the foreign purchaser understands that the product is not registered for use in the United States and cannot be sold in the United States.” 40 C.F.R. § 168.75(c)(1)(v).

9. For purposes of each of Section 17 of FIFRA, 7 U.S.C. § 136o, and 40 C.F.R. Part 168, a pesticide is registered for use and sale in the United States in accordance with the requirements and pursuant to the procedures set forth in, Section 3 of FIFRA, 7 U.S.C. § 136(a).

10. For purposes of 40 C.F.R. § 168.75(c), Respondent was the “exporter” for the aforementioned (¶ 8 of the “EPA Findings of Fact,” above) exports of Frontline Plus.

11. Each aforementioned (¶ 11 of the “EPA Findings of Fact,” above) failure to submit to EPA a Foreign Purchaser Acknowledgment statement constitutes an act prohibited by, and thus a violation of, 40 C.F.R. § 168.75(c), as a consequence of which each such failure constitutes an act made unlawful by, and thus a violation of, Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N).

12. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E) makes it “unlawful for any person in any State to distribute or sell to any person” a pesticide that is adulterated or misbranded, and pursuant to Section 2(q)(1)(H) of FIFRA, 7 U.S.C. § 136(q)(1)(H), a pesticide is “misbranded” if, with regard to a pesticide not registered in accordance with Section 3 of FIFRA, 7 U.S.C. § 136a, and intended for export, “the label does not contain [in a conspicuous manner] the following: ‘Not Registered for Use in the United States of America.’”

13. As a consequence of Respondent’s failure to include the words, “Not Registered for Use in the United States of America,” for each of the aforementioned (¶ 8 of the “EPA Findings of Fact, above) foreign-trade zone exportations, each such exportation constitutes an unlawful act (*i.e.* distribution of a pesticide that was misbranded) pursuant to, and thus a violation of, Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136(j)(a)(1)(E).

14. Respondent is liable pursuant to Section 14(a)(1) of FIFRA, 7 U.S.C. § 136l(a)(1) for:

- a) each of the aforementioned (¶s 6 and 11 of the “EPA Conclusions of Law, above) failures; and
- b) each of the aforementioned (¶ 13 of the “EPA Conclusions of Law, above) distributions.

AGREEMENT ON CONSENT

Based upon the foregoing, and pursuant to Section 14(a) FIFRA, as amended, 7 U.S.C. § 136l(a), and 40 C.F.R. § 22.18 of the “Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation or Suspension of Permits, 40 C.F.R. Part 22,” it is hereby agreed by and between Complainant and Respondent, and voluntarily accepted by Respondent, that, for purposes of this Consent Agreement and in the interest of settling this matter expeditiously without the time, expense or uncertainty of a formal adjudicatory hearing on the merits, Respondent: (a) admits that EPA has jurisdiction, pursuant to Section 14(a)(1) of FIFRA, 7 U.S.C. § 136l(a)(1), to prosecute an administrative proceeding for

the violations alleged above; (b) neither admits nor denies the “EPA Findings of Fact” or “EPA Conclusions of Law” as set forth in this document; (c) consents to the assessment of the civil penalty as set forth below; (d) consents to the issuance of the Final Order accompanying this Consent Agreement; and (e) waives its right to seek and obtain judicial review of, or otherwise contest, said Final Order.

Pursuant to 40 C.F.R. § 22.31(b), the executed CA/FO shall become effective and binding when filed with the Regional Hearing Clerk of the Agency, Region 2.

It is further hereby agreed by and between Complainant and Respondent, and voluntarily accepted by Respondent, that there shall be compliance with the following terms and conditions:

1. Respondent shall pay a civil penalty to EPA in the amount of **ONE HUNDRED THIRTY THOUSAND (\$130,000.00) DOLLARS**, to be paid within sixty (60) days of the date the Regional Administrator of EPA, Region 2, signs the Final Order accompanying this Consent Agreement.

Payment in accordance with the terms and schedule of this Consent Agreement shall be made by cashier’s check, certified check or by electronic fund transfer (EFT). If payment is made by cashier’s check or by certified check, such check shall be made payable to the “**Treasurer, United States of America,**” and shall be identified with a notation thereon listing the following: ***In re Merial (IA) LLP, Docket Number FIFRA-02-2011-5302***. If payment is made by either form of check, such payment shall be mailed to the following address:

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

Alternatively, if Respondent chooses to make payment by EFT, Respondent shall then provide the following information to its remitter bank when payment in accordance with the paragraph above is made:

- a. Amount of Payment
- b. SWIFT address: **FRNYUS33, 33 Liberty Street, New York, New York 10045**
- c. Account Code for Federal Reserve Bank of New York receiving payment: **68010727**
- d. Federal Reserve Bank of New York ABA routing number: **021030004**

2. Payment instructions:

a. Payment shall be in accordance with the instructions set forth in paragraph 1 of this section, above. If Respondent makes the payments by cashier's check or certified check, then such check shall be *received* at the above-listed address on or before the date specified. If Respondent makes the payments by the EFT method, then the EFT shall be *received* on or before the date specified.

b. Whether Respondent makes a payment by cashier's check, certified check or by the EFT method, Respondent shall promptly after payment has been made furnish reasonable proof that the required payment has been made, and such proof shall be furnished to both:

Lee A. Spielmann
Assistant Regional Counsel
Environmental Protection Agency, Region 2
290 Broadway, 16th floor
New York, New York 10007-1866

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

c. Failure to pay the specified amount in full within the time period set forth above may result in referral of this matter to the United States Department of Justice or the United States Department of the Treasury for collection.

d. Furthermore, if the required payment is not received on or before the date when it is made due under the terms of this document, interest therefor shall be assessed at the annual rate established by the Secretary of the Treasury pursuant to 31 U.S.C. § 3717, on the overdue amount from the date payment was to have been made through the date payment has been received. In addition, a late payment handling charge of \$15.00 will be assessed for each thirty (30) day period or any portion thereof, following the date payment was to have been received, in which payment of the amount remains in arrears. In addition, a 6% per annum penalty will be applied to any principal amount that has not been

received by the EPA within ninety (90) days of the date for which payment was required hereto to have been made.

3. The civil penalty provided for in this section constitutes a penalty within the meaning of 26 U.S.C. § 162(f).

4. By entering this Consent Agreement, Respondent hereby certifies to the best of the knowledge of its signatory herein that Respondent is in compliance with applicable FIFRA statutory and regulatory requirements with respect to any pesticide that it distributes and sells, offers for sale, holds for sale, holds for distribution and/or holds for shipment, and shall maintain such compliance, including compliance with those provisions cited above.

5. Complainant shall mail to Respondent (to the representative designated below) a copy of the fully executed CA/FO, and Respondent consents to service of the CA/FO upon it by an employee of EPA other than the Regional Hearing Clerk of EPA, Region 2:

Marshall V. Miller, Esq.
Miller & Company P.C.
4929 Main Street
Kansas City, Missouri 64112

6. Respondent has read this Consent Agreement, understands its terms, and consents to the issuance of the Final Order accompanying this Consent Agreement and consents to making full payment of the civil penalty in accordance with the terms and schedule set forth above.

7. This CA/FO is not intended, and shall not be construed, to waive, extinguish or otherwise affect Respondent's obligation to comply with all applicable federal, state and local law and regulations, nor is it intended or to be construed to be a ruling on or determination of any issue related to any federal, state or local permit.

8. This Consent Agreement is being voluntarily and knowingly entered into by the parties to resolve (conditional upon full payment of the civil penalty in accordance with the terms and conditions set forth herein) the administrative claims alleged above in the "EPA Findings of Fact" and the "EPA Conclusions of Law." Notwithstanding the above, nothing herein shall affect the right of the EPA or the United States to pursue appropriate injunctive relief or otherwise seek equitable relief or criminal sanctions for any violation of law arising from or otherwise resulting from Respondent distributing, selling, offering for sale, holding for sale, distribution or shipment of any pesticide.

9. Respondent shall ensure compliance with the provisions above cited, *viz.*:

a) For the foreign-trade zone admission or importation of any pesticide, Respondent shall ensure compliance with the applicable requirements of 19 C.F.R. § 12.112(a) regarding the submission to EPA of required "Notice[s]" of

Arrival of Pesticides and Devices”;

b) For the foreign-trade zone or other export of any pesticide intended solely for export to a foreign country and that has not been registered in accordance with Section 3 of FIFRA, 7 U.S.C. § 136(a), Respondent shall comply with the applicable requirements of 40 C.F.R. § 168.75(c) to include a “statement that indicates the foreign purchaser understands that the product is not registered for use in the United States and cannot be sold in the United States”; and

c) For any pesticide intended for export and that has not been registered in accordance with Section 3 of FIFRA, 7 U.S.C. § 136(a), Respondent shall ensure compliance with the applicable requirement of Section 2(q)(1)(H) of FIFRA, 7 U.S.C. § 136(q)(1)(H), that the label contain in a conspicuous manner the words, “Not Registered for Use in the United States of America.”

10. Respondent hereby waives its right to seek or to obtain any hearing on the on the terms and conditions set forth in the Consent Agreement and its accompanying Final Order and/or on the EPA Findings of Fact or EPA Conclusions of Law, above, or on any issue arising therefrom.

11. This Consent Agreement and any provision herein shall not be construed as an admission of liability in any adjudicatory or administrative proceeding, except in an action, suit or proceeding to enforce this Consent Agreement or any of its terms and conditions.

12. Respondent voluntarily waives any right or remedy it might have pursuant to 40 C.F.R. § 22.8 to be present during discussions with, or to be served with and reply to any memorandum or other communication addressed to, the Regional Administrator of EPA, Region 2, or the Deputy Regional Administrator of EPA, Region 2, where the purpose of such discussion, memorandum or other communication is to recommend that such official accept this Consent Agreement and issue the accompanying Final Order.

13. Each party shall bear its own costs and fees in connection with this proceeding.

14. The undersigned signatory for Respondent hereto certifies that: a) he or she is duly and fully authorized to enter into and ratify this Consent Agreement and all the terms and conditions set forth in this Consent Agreement, and b) he or she is duly and fully authorized to bind Respondent (including any successors) to comply with and abide by all the terms and conditions of this Consent Agreement.

In re Merial (IA) LLP

Docket Number FIFRA-02-2011-5302

~~_____~~

NAME: JORGE E. SOLE
[PRINT]

TITLE: VP INTERNATIONAL OPERATIONS

MERIAL LEGAL
JES
30 Aug 2011

DATE: 9 / 8 / 2011

COMPLAINANT:

~~_____~~
Dore LaPosta, Director
Division of Enforcement and Compliance
Assistance
U.S. Environmental Protection Agency -
Region 2

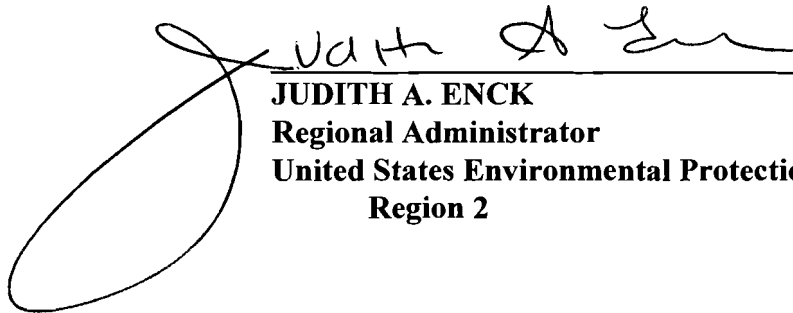
DATE: SEPTEMBER 14, 2011

In re Merial (IA) LLP
Docket Number FIFRA-02-2011-5302

FINAL ORDER

The Regional Administrator of EPA, Region 2, concurs in the foregoing Consent Agreement in the case of ***In the Matter of Merial (IA) LLP***, bearing Docket Number **FIFRA-02-2011-5302**. Said Consent Agreement, having been duly accepted and entered into by the parties, is hereby ratified and incorporated into this Final Order, which is hereby issued and shall take effect when filed with the Regional Hearing Clerk of EPA, Region 2. 40 C.F.R. § 22.31(b). This Final Order is being entered pursuant to the authority of 40 C.F.R. § 22.18(b)(3).

DATED: Sept 14, 2011
New York, New York



JUDITH A. ENCK
Regional Administrator
United States Environmental Protection Agency –
Region 2

In re Merial (IA) LLP
Docket No. FIFRA-02-2011-5302

CERTIFICATE OF SERVICE

I certify that I have this day caused to be sent the foregoing "CONSENT AGREEMENT AND FINAL ORDER," bearing docket number FIFRA-02-2011-5302, in the following manner to the respective addressees listed below:

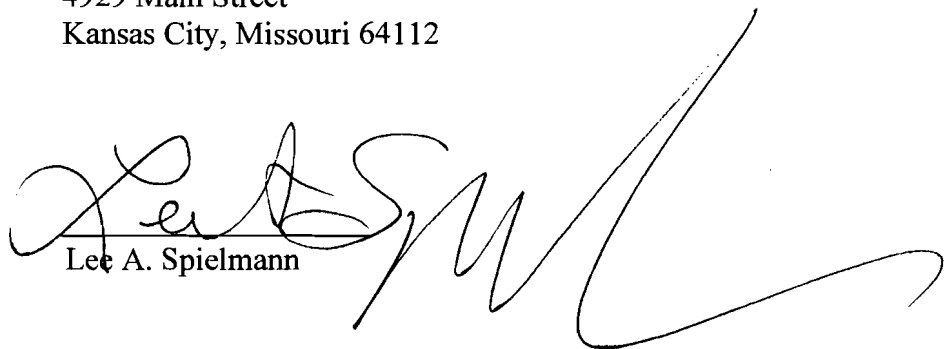
Original and One Copy
By Inter-Office Mail:

Office of Regional Hearing Clerk
U.S. Environmental Protection
Agency - Region 2
290 Broadway, 16th floor
New York, New York 10007-1866

Copy by Certified Mail,
Return Receipt Requested:

Marshall V. Miller, Esq.
Miller & Company P.C.
4929 Main Street
Kansas City, Missouri 64112

Dated: September 19, 2011
New York, New York


Lee A. Spielmann

