

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2003-0004; FRL-9923-28]

Access to Confidential Business Information by the Food and Drug Administration, Office of Foods and Veterinary Medicine

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has authorized, the Food and Drug Administration, Office of Foods and Veterinary Medicine (FDA), to access information which has been submitted to EPA under all sections of the Toxic Substances Control Act (TSCA) and Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Some of the information may be claimed or determined to be Confidential Business Information (CBI).

DATES: Access to the confidential data will occur no sooner than *[insert date 10 days after date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-1404; email address: lintner.colby@epa.gov.

Additional information on this activity can be obtained from: Scott M. Sherlock, Attorney Advisor, Office of Pollution Prevention and Toxics (OPPT), Office of Chemical Safety, Pesticides and Prevention (OCSPP), Environmental Protection Agency, 1200 Pennsylvania Ave., Washington, DC, 20460-0001; telephone number (202) 564-8257; email address: sherlock.scott@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to all who manufacture, process, or distribute industrial chemicals. Since other entities may also

be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How Can I Get Copies of this Document and Other Related Information?

The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2003-0004, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

II. What Action is the Agency Taking?

In the Spring of 2014, consistent with 40 CFR 2.209, the FDA requested access to information substances that may be present in foods (including animal food and feed), animal drugs, and cosmetics which is collected under the authority of the TSCA and FIFRA. This action gives notice that FDA will be given access to materials collected through the authority of TSCA and FIFRA, including information claimed as CBI. The access to this material is contemplated in a memorandum of understanding between the two agencies. The expectation is that the two agencies will share, on a reciprocal and as-needed basis, information, including non-public information, which may facilitate implementation of the agencies' respective programs. This activity is intended to maximize the utility of data collected under those statutes, and enhance the efficiency of the participants' regulatory processes and facilitate better risk management activities.

EPA is issuing this notice to inform all submitters of information under all sections of TSCA and FIFRA, that EPA may provide FDA access to these CBI materials on a need-to-know basis only. All access to TSCA and FIFRA CBI under this agreement will take place at FDA Headquarters located at 4300 River Road, College Park, MD.

Clearances for access to TSCA and FIFRA CBI under this arrangement may continue until terminated by either party.

FDA personnel will be briefed on appropriate security procedures before they are permitted access to the CBI.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: February 23, 2015.

Mario Caraballo,

Acting Director, Information Management Division, Office of Pollution Prevention and Toxics.

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