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Certifier	M. Bell

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 99D-2777]

**Guidance for Industry on Possible Dioxin/PCB Contamination in Drugs and Biological Products; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Possible Dioxin/PCB Contamination in Drugs and Biological Products." During January through June 1999, some poultry, swine, and ruminants in several European Union (EU) countries were fed with animal feed of Belgian origin contaminated with dioxins and polychlorinated biphenyls (PCB's). Manufacturers who are using materials derived from such animal sources in the manufacture of their products should verify that the materials they are using are not derived from animals affected during the contamination incident, or conduct suitable testing of the materials.

**DATES:** Written comments on this guidance may be submitted at any time. General comments on agency guidances are welcome at any time.

**ADDRESSES:** Submit written comments to:

1. Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for copies of this guidance to:

2. Office of Training and Communications, Division of Communications Management, Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug

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Administration, 5600 Fishers Lane, Rockville, MD 20857, <http://www.fda.gov/cder/guidance/index.htm>; or

3. Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448; <http://www.fda.gov/cber/guidelines.htm>; FAX: 1-888-CBERFAX or 301-827-3844, or call the Voice Information System at 800-835-4709 or 301-827-1800; or

4. Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), 7500 Standish Pl., Rockville, MD 20855; 301-594-1755, <http://www.fda.gov/cvm>.

**FOR FURTHER INFORMATION CONTACT:**

Eric P. Duffy, Center for Drug Evaluation and Research (HFD-325), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-0098;

Christopher C. Joneckis, Center for Biologics Evaluation and Research (HFM-20), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-5318; or

John C. Matheson, Center for Veterinary Medicine (HFV-200), Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855, 301-827-6649.

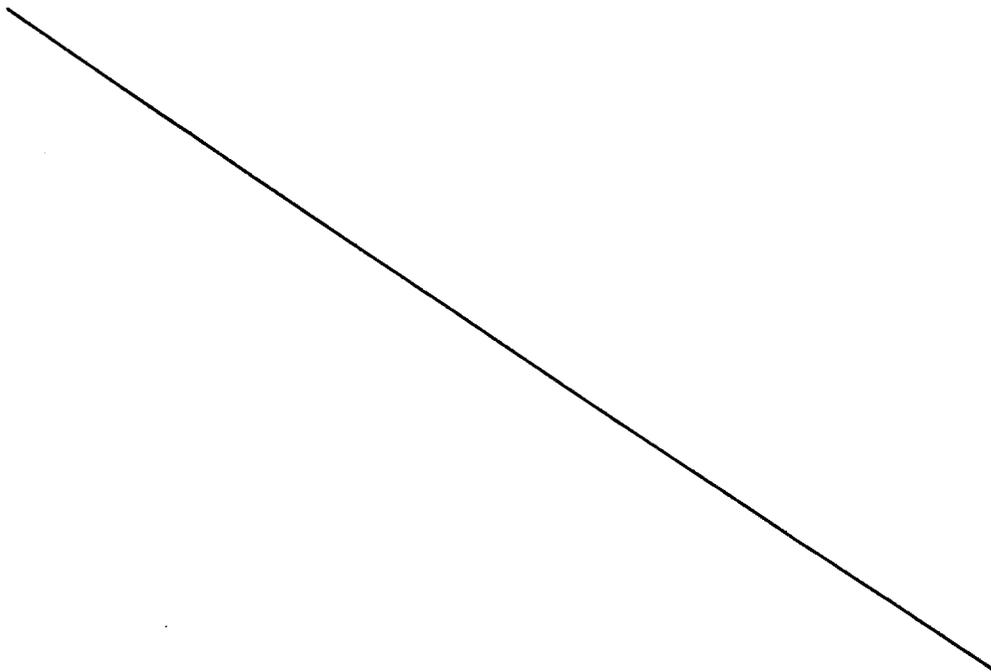
**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a guidance for industry entitled "Possible Dioxin/PCB Contamination in Drugs and Biological Products." During January through June 1999, some poultry, swine, and ruminants in several EU countries were fed with animal feed of Belgian origin contaminated with dioxins and PCB's. As a result, animals that received the contaminated feed have become contaminated with dioxins and PCB's. Manufacturers who are using materials derived from these animal sources in the manufacture of animal or human drug products or biological products should verify that the materials they are using are not derived from animals affected during the contamination incident, or conduct suitable testing of the materials.

This guidance document is being issued as a Level 1 guidance consistent with FDA's good guidance practices (62 FR 8961), February 27, 1997). It is being implemented immediately without prior public comment because of the potential hazard to the public health.

This guidance document may contain collections of information that require OMB clearance under the Paperwork Reduction Act of 1995. FDA will seek such approval and provide an opportunity for comment, as appropriate.

The guidance represents the agency's current thinking on the implications of dioxin/PCB contamination in animal and human drug products and biological products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

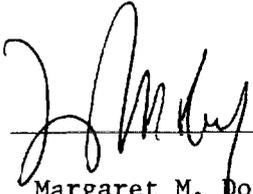
Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number



found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 8/19/99

August 19, 1999



Margaret M. Dotzel  
Acting Associate Commissioner for Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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