Guidance for Industry

Possible Dioxin/PCB Contamination of Drug and Biological Products

U.S. Department of Health and Human Services
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Compliance

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Internet: http://www.fda.gov/cder/guidance/index.htm.

or

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I. INTRODUCTION

This guidance is intended for manufacturers using materials derived from animal sources in the manufacture of human or animal drugs or biological products. During the period from January through June 1999, some poultry, swine, and ruminants (cattle, sheep, and goats) in several EU (European Union) countries were fed feed contaminated with dioxins and PCBs (polychlorinated biphenyls). As a result, animals that received the contaminated feed became contaminated with dioxins and PCBs. Manufacturers who are using materials from such animal sources in the manufacture of their products should verify that the materials they are using are not from animals affected during the contamination incident, or conduct suitable testing of the materials.

II. RECOMMENDATIONS FOR ASSESSING ANIMAL DERIVED MATERIALS

Because of the potential contamination of animals in Belgium, France, and the Netherlands, manufacturers should investigate the origin of animal derived materials (e.g. egg yolk lecithin, egg phospholipids, pancrelipase) they are using to manufacture human or animal drugs or biological products. This includes drug substances and excipients. If materials are found to be derived from poultry, swine, or ruminants, manufacturers should obtain certification from their suppliers that the animal derived materials (including the eggs from chickens) used in drugs or biological product manufacturing do not come from animals raised in any of these three countries during the period January through June 1999. If the animal source of manufacturing materials cannot be certified, the material should not be used to manufacture human or animal drugs or biological products. Alternatively, the materials should be tested for the presence of dioxins or PCBs prior to use. One analytical method suitable for foods that may be adapted for analyzing PCBs in pharmaceuticals can be found in the FDA's *Pesticide Analytical Manual*, Vol. 1, Chap. 3, sect. 303 or 304.[2]

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[1] This guidance has been prepared by the Food and Drug Administration. This guidance represents the Agency's current thinking on possible dioxin/PCB contamination of animal source material in EU countries. 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 statutes, regulations, or both.

[2] This is available on the FDA Web site (www.cfsan.fda.gov/~frf/pamil.html).

If products have already been produced using materials that cannot be certified, PCB or dioxin testing of the final product should be performed. If the presence of PCBs or dioxins is detected, manufacturers should contact the appropriate contact person listed below to discuss whether the release of the product is acceptable.

The Agency is conducting a sampling and testing program for dioxins and PCBs in drugs and biologics originating from EU countries.

Contact Persons

For animal drug products, contact John Matheson, Center for Veterinary Medicine, 301-827-6649.

For human drug products, contact Eric Duffy, Center for Drug Evaluation and Research, 301-827-7310.

For biological products, contact Christopher Joneckis, Center for Biologics Evaluation and Research, 301-827-5138.