DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-1305]

Multicriteria-Based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or "we") is announcing the availability of a risk assessment entitled "Multicriteria-Based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products." The risk assessment is a tool to assist with reevaluating which animal drug residues should be included in milk testing programs. We undertook this project in response to a request from the National Conference on Interstate Milk Shipments (NCIMS).

DATES: Submit either electronic or written comments on the risk assessment by **[INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments on the risk assessment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jane Van Doren, Center for Food Safety and Applied Nutrition (HFS-005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2927.

SUPPLEMENTARY INFORMATION:

I. Background

The NCIMS is a voluntary coalition that includes representatives from Federal and State governments, the dairy industry, academia, and consumer groups. FDA collaborates with the NCIMS under a memorandum of understanding between the two entities. The NCIMS requested that we conduct an assessment of animal drug residues in the milk supply to inform potential changes to milk testing program requirements. In response, we developed a multicriteria-based ranking model of selected animal drugs used in dairy cows. The risk assessment provides a science-based, analytical approach to collate and incorporate relevant available data and information (Ref. 1). It provides a decision-support tool to assist with reevaluating which animal drug residues should be included in milk testing programs. The risk assessment also may be used to identify and prioritize research needs. The risk assessment model approach has undergone an independent external peer review. FDA's response to the peer review is available electronically on the FDA Web site (Ref. 2).

The muticriteria-based ranking model is based on four overarching criteria that collectively contribute to a drug's score and rank within the group of drugs evaluated: (1) The likelihood that the drug will be administered to lactating dairy cows; (2) the likelihood that, following administration, drug residues would be present in milk (bulk tank or bulk milk pickup tanker); (3) the relative extent to which consumers could be exposed to the drug residue via consumption of milk and milk products; and (4) the potential for a human health hazard given

exposure to the drug residue. The risk assessment describes the ranking model structure, the scientific data and assumptions used to inform scoring in the model, and the ranking results. The risk assessment also identifies data gaps and research needs.

FDA invites comments that can help improve:

- The ranking model approach, including the specific criteria, scoring, and weighting scheme;
- the scientific data and assumptions used to inform scoring used in the model;
- the selection of animal drugs evaluated; and
- the clarity and the transparency of the risk assessment.

II. Comments

Interested persons may submit either electronic comments to http://www.regulations.gov or written comments to the Division of Dockets Management (see **ADDRESSES**) regarding the risk assessment. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

III. Electronic Access

Persons with access to the Internet may obtain the risk assessment at either http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm443549.htm or http://www.regulations.gov.

IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4

p.m. Monday through Friday, and are available electronically at http://www.regulations.gov. (We have verified the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. U.S. Food and Drug Administration (2015). "Multicriteria-Based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products." Accessible at http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm443549.htm.

2. U.S. Food and Drug Administration (2015). "Multicriteria-Based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products: Peer Review Report." Accessible at http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/default.htm.

Dated: April 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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