

guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: October 20, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0413]

Draft Guidance for Industry; Blue Bird Medicated Feed Labels; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#181) entitled "Draft Guidance for Industry: Blue Bird Medicated Feed Labels." This draft guidance is intended to provide new animal drug application (NADA) sponsors with the Center for Veterinary Medicine's (CVM's) current thinking on what constitutes recommended content and format of representative labels for new animal drugs intended for use in the manufacture of medicated feeds.

DATES: Submit written or electronic comments on the draft guidance by January 16, 2007, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance document to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that

office in processing your requests. Submit written comments on the draft guidance document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Dragan Momcilovic, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6856, e-mail: DMomcilo@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Draft Guidance for Industry: Blue Bird Medicated Feed Labels." This draft guidance is intended to provide NADA sponsors with CVM's current thinking on what constitutes recommended content and format of representative labels for new animal drugs intended for use in the manufacture of medicated feeds. An NADA for a Type A medicated article is required to include, among other things, representative labeling proposed to be used for Type B and Type C medicated feeds containing the new animal drug (21 CFR 514.1(b)(3)(v)(b)). A Type A medicated article is defined in § 558.3(b)(2) (21 CFR 558.3(b)(2)) as "intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed." Type B medicated feed is defined in § 558.3(b)(3) as "intended solely for the manufacture of other medicated feeds (Type B or Type C)." Type C medicated feed is defined in § 558.3(b)(4) as "intended as the complete feed for the animal or may be fed "top dressed" (added on top of usual ration) on or offered "free-choice" (e.g., supplement) in conjunction with other animal feed."

This draft guidance provides recommendations on the content and format of the representative labeling for Type B and Type C medicated feeds only. This representative labeling is also known as "Blue Bird" labeling. This draft guidance does not address the labeling of Type A medicated articles.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create

or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 514.1(b)(3) have been approved under OMB control number 0910-0032.

IV. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Electronic comments may be submitted on the Internet at <http://www.fda.gov/dockets/ecomments>. Once on the Internet site, select Docket No. 2006D-0413, "Draft Guidance for Industry: Blue Bird Medicated Feed Labels" and follow the directions. Copies of this draft guidance may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm>.

Dated: October 23, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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