Dated: October 23, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–18067 Filed 10–27–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0198]

Guidance for Industry on Implementation of Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Donors of Blood and Blood Components; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Implementation of Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Donors of Blood and Blood Components,'' dated October 2006. The guidance document provides blood establishments that collect blood and blood components intended for transfusion or for further manufacture with advice on reporting to FDA a manufacturing change consisting of the implementation of a standardized full-length donor history questionnaire and accompanying materials (DHQ documents). The guidance document addresses which DHQ documents are acceptable, and establishes the process for FDA to recognize other DHQ documents in the future. The guidance announced in this notice finalizes the draft guidance entitled ''Guidance for Industry: Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components'' dated April 2004.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance 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*.

FOR FURTHER INFORMATION CONTACT: Brenda R. Friend, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Implementation of Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Donors of Blood and Blood Components,'' dated October 2006. The guidance document provides blood establishments that collect blood and blood components intended for transfusion or for further manufacture with advice on reporting to FDA a manufacturing change consisting of the implementation of DHQ documents. Acceptable DHQ documents (DHQ documents that provide licensed and unlicensed manufacturers with one means of complying with the FDA requirements for collecting donor history information) will provide manufacturers with a specific process for administering questions to donors of blood and blood components to determine their eligibility to donate. The guidance document advises licensed manufacturers who choose to implement acceptable DHQ documents on how to report the manufacturing change to FDA, and recognizes the Donor History Questionnaire Version No. 1.1 dated June 2005 (v.DHQ–1.1), prepared by the AABB (formerly known as the American Association of Blood Banks) Donor History Task Force, as acceptable DHQ documents.

In the future, FDA may recognize other DHQ documents as acceptable, and intends to make all of the acceptable DHQ documents available on FDA's Web site. FDA believes that acceptable DHQ documents will assist manufacturers in complying with the regulations under 21 CFR 640.3 and 640.63. The guidance also advises licensed manufacturers of blood and blood components who choose to implement acceptable DHQ documents on how to report the manufacturing change to FDA under 21 CFR 601.12.

In the **Federal Register** of May 12, 2004 (69 FR 26399), FDA announced the availability of the draft guidance entitled ''Guidance for Industry: Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components'' dated April 2004. This draft guidance contained the full-length donor history questionnaire and accompanying materials (Version No. 1, dated April 2004) (v.DHQ–1). FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes to the guidance includes the following: (1) Added a statement to direct inquiries regarding the v.DHQ–1.1 or other AABB DHQ documents to the task force; (2) clarified how to implement acceptable DHQ documents, including v.DHQ–1.1, and the self-administration of these documents; and (3) added a separate Web site link to access all DHQ documents that FDA has recognized as acceptable. In addition, FDA received many comments on the v.DHQ–1, and forwarded these comments to the task force. In response, the task force submitted updated DHQ documents (v.DHQ–1.1), for FDA's review. The guidance announced in this notice finalizes the draft guidance dated April 2004, and refers to the v.DHQ–1.1.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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 and regulations.

II. Paperwork Reduction Act of 1995

This 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 606.160 have been approved under OMB control numbers 0910–0116; those in 21 CFR 601.12 have been approved under 0910–0338.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the

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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