degree that they chose to do so over the past 3 years and over the next 3 years will only need to reference these manuals on an as-needed basis. FDA estimates that, annually, approximately one half of the operators, 25,000, will choose to reference FDA's information, recommendations or model documents.

The number of regulator recordkeepers estimated in column 2 of Table 1 is based on FDA's estimate that there are approximately 3,000 State, local, territorial, and tribal regulatory jurisdictions. Gathering and reviewing reference material to develop practices for risk-based inspections of retail and food service establishments based on HACCP principles is a one-time burden. We assume that those 3,000 regulatory jurisdictions have utilized FDA's technical assistance manuals to the degree that they chose to do so over the past 3 years and over the next 3 years will only need to reference these manuals on an as-needed basis. FDA estimates that, annually, approximately one half of the regulatory jurisdictions (1,500) will choose to reference FDA's information, recommendations or model documents.

The hours per record estimated in column 2 of Table 1 are based on FDA's experience with similar technical assistance materials offered by the Agency. FDA estimates that over the next 3 years regulators and operators will only need to reference these manuals on an as needed basis. We estimate that it will take an operator with a specific need for information approximately 12 minutes (0.2 hour) to gather and record the data from the manuals. We estimate that it will take a regulator with a specific need for information approximately 15 minutes (0.25 hour) to gather and record the data from the manuals.

The total recordkeeping burden of the technical assistance manuals is 5,375 hours, as shown in Table 1.

Dated: November 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–27721 Filed 11–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1995–N–0031; (formerly Docket No. 1995N–0205)]

Compliance Guidance for Small Business Entities on Labeling for Bronchodilators: Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance guidance for small business entities entitled ''Labeling for Bronchodilators: Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Small Entity Compliance Guide.'' This guidance is intended to help small businesses understand and comply with the requirements of the final rule that provides new labeling applicable to all over-the-counter (OTC) bronchodilator drug products marketed without an approved application. The guidance describes the bronchodilator labeling requirements in plain language and provides answers to common questions on how to comply with the rule. This guidance was prepared in accordance with the Small Business Regulatory Fairness Act.

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

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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

FOR FURTHER INFORMATION CONTACT: Elaine Abraham, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 22, Rm. 5410, Silver Spring, MD 20993–0002, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a compliance guidance for small business entities entitled ''Labeling for Bronchodilators: Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Small Entity Compliance Guide.'' This small entity compliance guide applies to OTC bronchodilator drug products used to treat asthma that are marketed without an approved application (i.e., under the OTC bronchodilator monograph) (21 CFR part 341). OTC bronchodilators are those that contain any of the ephedrine ingredients (i.e., ephedrine, ephedrine hydrochloride, ephedrine sulfate, and racephedrine hydrochloride) or epinephrine ingredients (i.e., epinephrine, epinephrine bitartrate, and racepinephrine hydrochloride) listed under 21 CFR 341.16.

This guidance summarizes the July 26, 2011, final rule (76 FR 44475) regarding OTC bronchodilator drug products, which makes the following changes to the OTC regulations:

- Sets forth a new use statement, warnings (including an Asthma Alert warning), and directions that are required in the labeling of OTC bronchodilator drug products under 21 CFR 341.76.
- Revises labeling requirements for OTC bronchodilator drug products to ensure consistency with the standardized Drug Facts content and formatting requirements set forth in 21 CFR 201.66.

Manufacturers must be in compliance with the rule beginning on January 23, 2012.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on labeling for OTC bronchodilator drug 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 statutes and regulations.

II. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* 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 document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: November 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–27724 Filed 11–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0799]

Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components, Including Source Plasma, To Reduce the Risk of Transmission of Hepatitis B Virus; 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: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components, including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B Virus,'' dated October 2012. The guidance document provides recommendations on the use of FDA-licensed nucleic acid tests (NAT) to screen blood donors for hepatitis B virus (HBV) deoxyribonucleic acid (DNA) and recommendations for product testing and disposition, donor management, methods for donor requalification, and product labeling. In addition, the guidance provides notification that FDA considers the use of an FDA-licensed HBV NAT to be necessary to reduce adequately and appropriately the risk of transmission of HBV. The guidance is intended for blood establishments that collect Whole Blood and blood components for transfusion or for further manufacture, including recovered plasma, Source Plasma and Source Leukocytes. The guidance announced in this notice finalizes the draft guidance of the same title, dated November 2011. The guidance also supplements previous memoranda and guidance from FDA concerning the testing of donations for hepatitis B surface antigen (HBsAg) and antibody to hepatitis B core antigen (anti-HBc) and the management of donors and donations mentioned in those documents.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (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 electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., 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: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components, including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B Virus,'' dated October 2012. FDA is providing blood establishments that collect Whole Blood and blood components for transfusion or for further manufacture, including recovered plasma, Source Plasma and Source Leukocytes, with recommendations concerning the use of FDA-licensed NAT to screen blood donors for HBV DNA. FDA is also providing these blood establishments with recommendations for product testing and disposition, donor management, methods for donor requalification, and product labeling.

In addition, FDA is notifying those blood establishments that FDA considers the use of an FDA-licensed HBV NAT to be necessary to reduce adequately and appropriately the risk of transmission of HBV. FDA-licensed HBV NAT can detect evidence of infection at an earlier stage than is possible using previously approved HBsAg and anti-HBc tests. Therefore, FDA is recommending the use FDA-licensed HBV NAT, in accordance with the requirements under Title 21 Code of Federal Regulations, 610.40(a) and (b) (21 CFR 610.40(a) and (b)).

The guidance supplements previous memoranda and guidance from FDA to blood establishments concerning the testing of donations for HBsAg and anti-HBc, and the management of donors and donations mentioned in those documents. Note that testing Whole Blood and blood components for transfusion and Source Leukocytes for further manufacture for HBsAg and anti-HBc, and Source Plasma for HBsAg, should continue when a blood establishment implements HBV NAT. FDA may consider advancements in technology for testing blood donations, as well as data obtained following the implementation of HBV NAT, to make future recommendations on adequate and appropriate testing for HBV.

In the **Federal Register** of November 28, 2011 (76 FR 72950), FDA announced the availability of the draft guidance of the same title, dated November 2011. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In addition to minor editorial changes made to improve clarity, changes to the draft guidance include revised labeling recommendations and an extension of the time for implementation of the guidance to 6 months after publication of the final guidance. The guidance announced in this notice finalizes the draft guidance dated November 2011.

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 requirement 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