Interstate Shellfish Dealer's Certificate (OMB Control Number 0910–0021)—Extension

Under 42 U.S.C. 243, FDA is required to cooperate with and aid State and local authorities in the enforcement of their health regulations and is authorized to assist States in the prevention and suppression of communicable diseases. Under this authority, FDA participates with State regulatory agencies, some foreign nations, and the molluscan shellfish industry in the National Shellfish Sanitation Program (NSSP).

NSSP is a voluntary, cooperative program to promote the safety of molluscan shellfish by providing for the classification and patrol of shellfish growing waters and for the inspection and certification of shellfish processors. Each participating State and foreign nation monitors its molluscan shellfish processors and issues certificates for those that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provides a certificate of its certified shellfish processors to FDA on Form FDA 3038, ''Interstate Shellfish Dealer's Certificate.'' FDA uses this information to publish the ''Interstate Certified Shellfish Shippers List,'' a monthly comprehensive listing of all molluscan shellfish processors certified under the cooperative program. If FDA did not collect the information necessary to compile this list, participating States would not be able to identify and keep out shellfish processed by uncertified processors in other States and foreign nations. Consequently, NSSP would not be able to control the distribution of uncertified and possibly unsafe shellfish in interstate commerce, and its effectiveness would be nullified.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of Interstate Shellfish Dealer's Certificate	3038	40	57	2,280	0.10	228

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that 40 respondents will submit 2,280 Interstate Shellfish Dealer's Certificates annually, for a total burden of 228 hours (2,280 submissions × 0.10 hours = 228 hours). This estimate is based on FDA's experience and the number of certificates received in the past 3 years.

Dated: November 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–27722 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–2012–N–1105]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Hazard Analysis and Critical Control Point Manuals for Operators and Regulators of Retail and Food Service Establishments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with FDA's technical assistance reference manuals provided to State, local, territorial, and tribal jurisdictions, and other Federal Agencies to interpret and promote the application of Hazard Analysis and Critical Control Point (HACCP) principles to reduce the risk of foodborne illness in the operation of retail and food service establishments.

DATES: Submit either electronic or written comments on the collection of information by January 14, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, *domini.bean@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the

collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Voluntary Hazard Analysis and Critical Control Point Manuals for Operators and Regulators of Retail and Food Service Establishments (OMB Control Number 0910–0578)—Extension

HACCP principles are designed to reduce the occurrence of foodborne illness risk factors through preventive controls. FDA has developed two technical assistance reference manuals that interpret and promote the application of HACCP principles to reduce the risk of foodborne illness in the operation of retail and food service establishments.

The responsibility and authority for regulating retail and food service establishments lie primarily with State and local governments. Officials in State, local, territorial, and tribal agencies inspect these food facilities, license establishments, issue permits, and enforce their State or local government's laws and regulations. FDA's Retail Food Protection Program provides assistance to the more than 3,000 State and local government agencies that regulate the retail food industry nationally. The primary objective of the Retail Food Protection Program is to prevent foodborne illness at the retail level of the food industry by directing activities toward promotion of effective State and local regulatory programs. FDA provides assistance to State, local, territorial, and tribal regulatory jurisdictions through multiple means including, but not limited to, training and technical assistance. Authority for providing such assistance is derived from section 311 of the Public Health Service Act (42 U.S.C. 243). In addition, FDA's mission under section 903(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(b)(2)(A)) includes ensuring that foods are safe, wholesome, and sanitary, and section 903(b)(4) of the FD&C Act directs FDA to cooperate with food retailers, among others, in carrying out this part of its mission.

The first manual, entitled ''Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments'' (Operator's Manual) (available at *http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/Operators/default.htm*), provides operators of retail and food service establishments a roadmap for developing a food safety management system based on HACCP principles. Food safety management systems allow establishment operators to take a proactive role in ensuring that the food served or sold in their establishment is safe. Rather than responding to a foodborne illness when it occurs, they can prevent it by taking active steps to eliminate, prevent, or reduce to an acceptable level food safety hazards that may cause someone to become sick or injured.

The second manual, entitled ''Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems'' (Regulator's Manual) (available at *http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/Regulators/default.htm*), provides State, local, territorial, and tribal regulatory authorities with a model for prioritizing inspections using a risk-based approach. The Regulator's Manual provides a roadmap for evaluating retail and food service establishments based on the application of HACCP principles.

FDA developed the manuals as technical assistance reference resources for regulators and operators to help reduce the risk of foodborne illness. There is no Federal requirement that retail and food service establishments implement food safety management systems based on HACCP principles. State, local, territorial, and tribal regulatory authorities decide whether to require food safety management systems in the operation of retail and food service establishments. Regulators and operators will not submit information to FDA based on these manuals.

Regulators and retail and food service operators use the manuals as technical assistance reference resources. The Regulator's Manual contains information, recommendations and model documents for State, local, territorial, and tribal regulators who wish to develop practices for risk-based inspections of retail and food service establishments based on the application of HACCP principles. The Operator's Manual contains information, recommendations and model documents for operators of retail and food service establishments who wish to develop and/or validate the practices used in a food safety management system based on HACCP principles.

Description of Respondents: The respondents are State, local, territorial, and tribal regulatory jurisdictions and operators of retail and food service establishments in the United States. Respondents are from both the public sector (State, local, territorial, and tribal governments) and the private sector (for-profit businesses).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
Reference of Technical Assistance Manuals by Operators ..	25,000	1	25,000	0.2 (12 minutes) ...	5,000
Reference of Technical Assistance Manuals by Regulators	1,500	1	1,500	0.25 (15 minutes)	375
Total	.....	.....	.....	.....	5,375

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of operator recordkeepers estimated in column 2 of Table 1 is based on FDA's goal to have 50,000 (½ of 1 percent) of the approximately one million U.S. retail and food service operators implement the recommendations outlined in the two manuals, as estimated in 2009 (73 FR 77721, at 77722). FDA's estimate of the total number of retail and food service establishments is based on numbers obtained from the two major trade organizations representing these industries, the Food Marketing Institute and the National Restaurant Association. Gathering reference material to develop and/or validate food safety management system practices is a one-time burden. We assume that those 50,000 operators 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 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]

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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