Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 6, 2015. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 3, 2015. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. 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. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–10999 Filed 5–6–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0138]

Questions and Answers Regarding Mandatory Food Recalls; Draft Guidance for Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry on the implementation of the mandatory food recall provisions of the FDA Food Safety Modernization Act (FSMA). The guidance is in the form of Questions and Answers and provides answers to common questions that might arise about the mandatory recall provisions and FDA's plans for their implementation.

DATES: Although you may comment on any guidance at any time, to ensure that the Agency considers your comments on this draft guidance before it completes a final version of the guidance, submit electronic or written comments on the draft guidance by July 6, 2015.

ADDRESSES: Submit written requests for single copies of the guidance to the Outreach and Information Center (HFS–009), Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

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: Cecilia M. Wolyniak, Food and Drug Administration, WO32 Rm. 4352 HFC–210, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8209.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's mandatory food recall authority went into effect when FSMA was enacted on January 4, 2011. Section 423 of the Federal Food, Drug and Cosmetic Act (FD&C Act), as added by section 206 of FSMA, gives FDA the authority to order a responsible party to recall an article of food where FDA determines that there is a reasonable probability that the article of food (other than infant formula) is adulterated under section 402 of the FD&C Act [21 U.S.C. 342] or misbranded under section 403(w) of the FD&C Act [21 U.S.C. 343(w)] and that the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals (SAHCODHA).

FDA is announcing the availability of a draft guidance for industry entitled ''Questions and Answers Regarding Mandatory Food Recalls; Draft Guidance for Industry.'' The draft guidance provides answers to common questions that might arise about the mandatory recall provisions and FDA's plans for their implementation.

This guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our 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 does not refer to any information collection provisions found in FDA regulations. 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). We conclude that the Draft Guidance for Industry: Questions and Answers Regarding Mandatory Food Recalls is not subject to Paperwork Reduction Act of 1995.

III. Comments

Interested persons may submit either written comments regarding the guidance to the Division of Dockets Management (see **ADDRESSES**) or electronic comments regarding the guidance 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: May 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11009 Filed 5–6–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2029]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Administrative Practices and Procedures; Formal Evidentiary Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 8, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0191. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Administrative Practices and Procedures (21 CFR 10.30, 10.33.10.35.10.85); Formal Evidentiary Public Hearing (21 CFR 12.22, 12.45) (OMB Control Number 0910–0191)—Extension

The Administrative Procedures Act (5 U.S.C. 553(e)) provides that every Agency shall give an interested person the right to petition for issuance, amendment, or repeal of a rule. Section 10.30 (21 CFR 10.30) sets forth the format and procedures by which an interested person may submit to FDA, in accordance with § 10.20 (21 CFR 10.20) (Submission of documents to Division of Dockets Management), a citizen petition requesting the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants. Respondents are individuals or households, State or local governments, and not-for-profit institutions or groups.

Section 10.33 (21 CFR 10.33), issued under section 701(a) of the Federal, Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 371(a)), sets forth the format and procedures by which an interested person may request reconsideration of part or all of a decision of the Commissioner on a petition submitted under 21 CFR 10.25 (Initiation of administrative proceedings). A petition for reconsideration must contain a full statement in a well-organized format of the factual and legal grounds upon which the petition relies. The grounds must demonstrate that relevant information and views contained in the administrative record were not previously or not adequately considered by the Commissioner. The respondent must submit a petition no later than 30 days after the decision involved. However, the Commissioner may, for good cause, permit a petition to be filed after 30 days. An interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision. FDA uses the information provided in the request to determine whether to grant the petition for reconsideration. Respondents to this collection of information are individuals of households, State or local governments, not-for-profit institutions, and businesses or other for-profit institutions who are requesting from the Commissioner of FDA a reconsideration of a matter.

Section 10.35 (21 CFR 10.35), issued under section 701(a) of the FD&C Act, sets forth the format and procedures by which an interested person may request, in accordance with § 10.20 (Submission of documents to Division of Dockets Management), the Commissioner to stay the effective date of any administrative action.

Such a petition must do the following: (1) Identify the decision involved; (2) state the action requested, including the length of time for which a stay is requested; and (3) include a statement of the factual and legal grounds on which the interested person relies in seeking the stay. FDA uses the information provided in the request to determine whether to grant the petition for stay of action.

Respondents to this information collection are interested persons who choose to file a petition for an administrative stay of action.

Section 10.85 (21 CFR 10.85), issued under section 701(a) of the FD&C Act, sets forth the format and procedures by which an interested person may request, in accordance with § 10.20 (Submission of documents to Division of Dockets Management), an advisory opinion from the Commissioner on a matter of general applicability. An advisory opinion represents the formal position of FDA on a matter of general applicability. When making a request, the petitioner must provide a concise statement of the issues and questions on which an opinion is requested, and a full statement of the facts and legal points relevant to the request. Respondents to this collection of information are interested persons seeking an advisory opinion from the Commissioner on the Agency's formal position for matters of general applicability.

FDA has developed a method for electronic submission of citizen petitions. The Agency still allows for non-electronic submissions; however, electronic submissions of a citizen petition to a specific electronic docket presents a simpler and more straightforward approach. FDA has created a single docket on *http://www.regulations.gov,* the U.S. Government's consolidated docket Web site for Federal Agencies, for the initial electronic submission of all citizen petitions. The advantage to this change is that it ensures efficiency and ease in communication, quicker interaction between citizen petitioners and FDA, and easier access to FDA to seek input through the citizen petition process.

The regulations in 21 CFR 12.22, issued under section 701(e)(2) of the FD&C Act (21 U.S.C. 371(e)(2)), set forth the instructions for filing objections and requests for a hearing on a regulation or order under § 12.20(d) (21 CFR 12.20(d)). Objections and requests must be submitted within the time specified in § 12.20(e). Each objection, for which a hearing has been requested, must be separately numbered and specify the provision of the regulation or the proposed order. In addition, each objection must include a detailed description and analysis of the factual information and any other document, with some exceptions, supporting the objection. Failure to include this information constitutes a waiver of the right to a hearing on that objection. FDA uses the description and analysis to determine whether a hearing request is justified. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under 21 CFR 12.24 and does not limit the evidence that may be presented if a hearing is granted.

Respondents to this information collection are those parties that may be adversely affected by an order or regulation.

Section 12.45 (21 CFR 12.45) issued under section 701 of the FD&C Act (21 U.S.C. 371), sets forth the format and procedures for any interested person to

file a petition to participate in a formal evidentiary hearing, either personally or through a representative. Section 12.45 requires that any person filing a notice of participation state their specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. This section also requires that the notice include a statement that the person will present testimony at the hearing and will comply with specific requirements in 21 CFR 12.85, or, in the case of a hearing before a Public Board of Inquiry, concerning disclosure of data and information by participants (21 CFR 13.25). In accordance with § 12.45(e) the presiding officer may omit a participant's appearance.

The presiding officer and other participants will use the collected information in a hearing to identify specific interests to be presented. This preliminary information serves to expedite the prehearing conference and commits participation.

The respondents are individuals or households, State or local governments, not-for-profit institutions and businesses, or other for-profit groups and institutions.

In the **Federal Register** of December 10, 2014 (79 FR 73320), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
10.30—Citizen Petition	207	1	207	24	4,968
10.33—Administrative reconsideration of action	4	1	4	10	40
10.35—Administrative Stay of Action	5	1	5	10	50
10.85—Advisory Opinions	4	1	4	16	64
12.22—Filing Objections and Requests for a Hearing on a Regulation or Order	3	1	3	20	60
12.45—Notice of Participation	4	1	4	3	12
Total					5,194

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

The burden estimates for this collection of information are based on Agency records and experience over the past 3 years.

Dated: May 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–10996 Filed 5–6–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–E–1690]

Determination of Regulatory Review Period for Purposes of Patent Extension; SYNRIBO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SYNRIBO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Campus, Rm. 3180, Silver Spring, MD 20993, 301–796–7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product SYNRIBO (omacetaxine mepesuccinate). SYNRIBO is indicated for treatment of adult patients with chronic or accelerated phase chronic myeloid leukemia with resistance and/or intolerance to two or more tyrosine kinase inhibitors. Subsequent to this approval, the USPTO received a patent term restoration application for SYNRIBO (U.S. Patent No. 6,987,103) from Robin, Mahon, Maisonneuve, Maloisel, and Blanchard, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 30, 2014, FDA