DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1119]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers

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 September 15, 2014.

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 0910–0037. 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.

Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers—21 CFR 108.25 and 108.35, and Parts 113 and 114 (OMB Control Number 0910–0037)—Revision

Section 402 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342) deems a food to be adulterated, in part, if the food bears or contains any poisonous or deleterious substance which may render it injurious to health. Section 301(a) of the FD&C Act (21 U.S.C. 331(a)) prohibits the introduction or delivery for introduction into interstate commerce of adulterated food. Under section 404 of the FD&C Act (21 U.S.C. 344), our regulations require registration of food processing establishments, filing of process or other data, and maintenance of processing and production records for acidified foods and thermally processed low-acid foods in hermetically sealed containers. These requirements are intended to ensure safe manufacturing, processing, and packing procedures and to permit us to verify that these procedures are being followed. Improperly processed low-acid foods present life-threatening hazards if contaminated with foodborne microorganisms, especially *Clostridium botulinum.* The spores of *C. botulinum* need to be destroyed or inhibited to avoid production of the deadly toxin that causes botulism. This is accomplished with good manufacturing procedures, which must include the use of adequate heat processes or other means of preservation.

To protect the public health, our regulations require that each firm that manufactures, processes, or packs acidified foods or thermally processed low-acid foods in hermetically sealed containers for introduction into interstate commerce register the establishment with us using Form FDA 2541 (§§ 108.25(c)(1) and 108.35(c)(2) (21 CFR 108.25(c)(1) and 108.35(c)(2))). In addition to registering the plant, each firm is required to provide data on the processes used to produce these foods, using Form FDA 2541a for all methods except aseptic processing, or Form FDA 2541c for aseptic processing of low-acid foods in hermetically sealed containers (§§ 108.25(c)(2) and 108.35(c)(2)). Plant registration and process filing may be accomplished simultaneously. Process data must be filed prior to packing any new product, and operating processes and procedures must be posted near the processing equipment or made available to the operator (21 CFR 113.87(a)).

Regulations in parts 108, 113, and 114 (21 CFR parts 108, 113, and 114) require firms to maintain records showing adherence to the substantive requirements of the regulations. These records must be made available to FDA on request. Firms also must document corrective actions when process controls and procedures do not fall within specified limits (§§ 113.89, 114.89, and 114.100(c)); report any instance of potential health-endangering spoilage, process deviation, or contamination with microorganisms where any lot of the food has entered distribution in commerce (§§ 108.25(d) and 108.35(d) and (e)); and develop and keep on file plans for recalling products that may endanger the public health (§§ 108.25(e) and 108.35(f)). To permit lots to be traced after distribution, acidified foods and thermally processed low-acid foods in hermetically sealed containers must be marked with an identifying code (§§ 113.60(c) (thermally processed foods) and 114.80(b) (acidified foods)).

The records of processing information are periodically reviewed during factory inspections by FDA to verify fulfillment of the requirements in 21 CFR parts 113 or 114. Scheduled thermal processes are examined and reviewed to determine their adequacy to protect public health. In the event of a public health emergency, records are used to pinpoint potentially hazardous foods rapidly and thus limit recall activity to affected lots.

As described in our regulations, processors may obtain the paper versions of Forms FDA 2541, FDA 2541a, and FDA 2541c by contacting us at a particular address. Processors mail completed paper forms to us. However, processors who are subject to §§ 108.25, 108.35, or both, have an option to submit Forms FDA 2541, FDA 2541a, and FDA 2541c electronically (see 76 FR 11783 at 11785, March 3, 2011).

In a notice published in the **Federal Register** of September 18, 2013 (78 FR 57391) (the September 18, 2013 notice), we provided notice that we are updating the process filing portion of the electronic submission system to incorporate ''smartform'' technology. The updated process filing portion of the electronic submission system will query the processor about the processes used to produce the food and present only those data entry fields that are applicable. This will reduce the burden on processors and reduce errors in process filing because processors will no longer need to evaluate whether particular data entry fields are applicable to their products. For example, when a processor submits a process filing for a product that is processed using a low-acid retorted method with a process mode of ''agitating,'' smartform technology would bypass questions that are not applicable to this process mode option.

Although we encourage commercial processors to use the electronic submission system for plant registration and process filing, we will continue to make paper-based forms available. To standardize the burden associated with process filing, regardless of whether the process filing is submitted electronically or using a paper form, we are proposing to eliminate Forms FDA 2541a and FDA

2541c and replace these two forms with a total of four forms. Each of the four proposed replacement forms will pertain to a specific type of commercial processing and will be available both on the electronic submission system and as a paper-based form. The electronic submission system and the paper-based form will ''mirror'' each other to the extent practicable. The four proposed replacement process filing forms are as follows:

- Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method);
- Form FDA 2541e (Food Process Filing For Acidified Method);
- Form FDA 2541f (Food Process Filing for Water Activity/Formulation Control Method); and
- Form FDA 2541g (Food Process Filing for Low-Acid Aseptic Systems).

Some of the data entry fields on the four proposed replacement process filing forms are not on current Forms FDA 2541a and FDA 2541c. We added certain data entry fields to improve the efficiency of our review of the process filings. For example, the four proposed replacement forms include data entry fields for the ''food product group'' (such as liquid, ready-to-eat ''breakfast foods''). We estimate that any time it would take to provide such information not already on Form FDA 2541a or FDA 2541c would be offset by the time processors will save by not having to evaluate whether certain data entry fields on Form FDA 2541a or FDA 2541c are applicable to their products.

In accordance with 5 CFR 1320.8(d), we requested public comment on the proposed information collection in the September 18, 2013, notice. We extended the comment period for an additional 90 days on November 18, 2013. We received five comments in response to the notice, each addressing one or more topics.

(Comment 1) One comment expressed concern that it would have to resubmit all previously submitted process filings.

(Response) There is no need to resubmit previously submitted process filings. Previously submitted process filings will remain valid provided that the information in the previously submitted filings is still current.

(Comment 2) One comment expressed concern that we are planning to eliminate electronic submission.

(Response) We are not planning to eliminate electronic submission for process filing and registration. When we published the notice on September 18, 2013, we made the revised paper forms available for review so that interested parties could comment on their content and format. As a result of the comments, we have updated the draft revised forms. Once we receive OMB approval of the revised information collection, we will update the electronic system so that the information requested in the electronic system mirrors the information requested on the revised paper forms.

(Comment 3) One comment asserted that we do not have legal authority to use Form FDA 2541e for the purpose of submitting a voluntary process filing.

(Response) We disagree with the comment's assertion that we do not have the legal authority to permit a manufacturer to provide a voluntary process filing submission to FDA on Form FDA 2541e. The scope of the voluntary submission discussed in this document is limited to certain food products (that is, fermented foods that have a finished equilibrium pH of 4.6 or below and acid foods with small amounts of added low-acid ingredients) whose regulatory classification is not obvious when we look at the product and the product label. FDA has long regarded it to be a prudent practice for manufacturers of foods to work cooperatively with FDA to ensure that their products are safe and comply with all applicable legal requirements. Consequently, we have proposed to institute the voluntary consultation process discussed in this document. The draft guidance document, ''Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g (Food Process Filing Forms) to FDA in Electronic or Paper Format (January 2014),'' available on FDA's Web site at *http://www.fda.gov/FoodGuidances,* describes the scope and purpose of this process in section II.C, and we expect to issue final guidance on or about the date that Form FDA 2541e becomes operational, along with the other revised forms discussed in this document. The ability to submit a voluntary submission fosters communication by encouraging manufacturers to submit their processing techniques to FDA for an early evaluation of whether their product satisfies the criteria for being excluded from the coverage of part 114. Such communication will help to ensure that any potential food safety issues are resolved before the product is marketed and will help to ensure that processing techniques used by manufacturers are in full compliance with the standards of the FD&C Act. FDA is instituting this voluntary consultation process under our broad statutory authority, found in section 1003 of the FD&C Act (21 U.S.C. 393), to protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled and the prohibitions regarding adulterated food in section 402(a)(1) of the FD&C Act (21 U.S.C. 342(a)(1)).

(Comment 4) One comment expressed concern that a manufacturer of a product that satisfies the criteria for being excluded from the coverage of part 114 who submits a voluntary submission will be held to the same regulations that acidified products are held to with regard to inspections and recordkeeping. As a result, we would be making substantial changes to part 114 without notice and comment rulemaking.

(Response) A voluntary process filing submission to FDA on Form FDA 2541e allows manufacturers to submit their processing techniques to FDA for an early evaluation of whether their product satisfies the criteria for being excluded from the coverage of part 114. If the product satisfies the criteria for being excluded from the coverage of part 114, the product is not subject to the inspection and recordkeeping regulations in part 114 and has not become subject to those regulations as a result of the submission and consultation. However, if after careful review of the voluntary submission we conclude that the product does not satisfy the criteria for being excluded from the coverage of part 114, then we would advise the manufacturer of our determination that the product is an acidified food subject to part 114 and that a process filing as an acidified food must be submitted for the product.

(Comment 5) One comment expressed concern that the ''voluntary process filing'' is not ''voluntary'' because it asserted our inspectors will expect all manufacturers of products that are excluded from the coverage of part 114 to voluntarily file, thereby making the process effectively mandatory.

(Response) The voluntary submission process is only available to manufacturers of certain food products (that is, fermented foods that have a finished equilibrium pH of 4.6 or below and acid foods with small amounts of added low-acid ingredients) whose regulatory classification is not obvious when we look at the product and the product label. For example, we can easily determine that products such as refrigerated foods and carbonated beverages are excluded from the coverage of part 114 by looking at the product or the product label. In response to comments, we have revised our guidance and the instructions for voluntary submissions to clarify those products for which a voluntary

submission would or would not be accepted. In the event that we receive a voluntary submission for a product that is not eligible for the review, we will respond to the submission by notifying the manufacturer of the error. We will not add the product to our database. Thus, ineligible submissions will be rejected and will not result in additional information in our database. In summary, our inspectors will not expect all manufacturers to submit voluntary submissions because not all products are eligible for the process and no advantage is obtained from a voluntary submission for an ineligible product.

(Comment 6) One comment expressed concern that voluntary submitters who choose to use the electronic submission system would not be able to access and view their submissions.

(Response) A voluntary submission on Form FDA 2541e that is submitted electronically may be accessed and viewed in the same manner as a required process filing on Form FDA 2541e that is submitted electronically.

(Comment 7) One comment suggested that voluntary submission may create confusion by subjecting a non-covered product (that is a refrigerated food or a fermented food) to the acidified food regulations,

(Response) As discussed in the response to Comment 4, if a product satisfies the criteria for being excluded from the coverage of part 114, the product is not subject to the inspection and recordkeeping regulations in part 114 and will not become subject to those regulations as a result of a voluntary submission. We can easily determine that some products such as refrigerated foods and carbonated beverages are excluded from the coverage of part 114 by looking at the product or the product label. The voluntary submission process is only available to manufacturers of certain food products (that is, fermented foods that have a finished equilibrium pH of 4.6 or below and acid foods with small amounts of added low-acid ingredients) whose regulatory classification is not obvious when we look at the product and the product label.

(Comment 8) One comment stated that the current, ''Acidified and Low-Acid Canned Foods: Draft Guidance: Acidified Foods (September, 2010),'' does not provide guidance on what constitutes a fermented food.

(Response) As discussed in section III.C of the guidance, fermented foods (such as some kinds of sauerkraut, cucumber pickles, and green olives) are low acid foods that have been subjected to the action of microorganisms to reduce the pH of the food to 4.6 or below.

(Comment 9) One comment suggested that the voluntary submission process creates unnecessary burdens for both industry and FDA and that there will be no benefit derived from the consultation process.

(Response) Manufacturers are free to decide whether to make a voluntary submission, and we believe that some manufacturers may choose to do so to participate in the voluntary consultation process. Such consultation may enable us to more easily determine the regulatory classification of a product. For a domestic product, this may reduce the time it takes for us to complete a facility inspection. With regard to a food product that will be offered for import into the United States, this may enable us to reduce the time it takes to authorize release of the product at the border. For FDA, the voluntary submission results in increased efficiency.

(Comment 10) Because FDA Form 2541e does not have to be filled out in its entirety, the comment argued that voluntary filing does not result in benefits to food safety. The comment suggested that a better voluntary program would be one in which a processor could submit a scheduled process for a food to seek our assessment of the systems in place to assure the safety of the food, not just as a way to determine if a product is acidified or not.

(Response) As discussed in the response to Comment 4, a voluntary process filing submission to FDA on Form FDA 2541e allows manufacturers to submit their processing techniques to FDA for an early evaluation of whether their product satisfies the criteria for being excluded from the coverage of part 114. If we conclude that the product does not satisfy the criteria for being excluded from the coverage of part 114, then we would advise the manufacturer of our determination that the product is an acidified food subject to part 114 and that a process filing as an acidified food must be submitted for the product. This results in proper regulatory classification of the product and appropriate FDA review of the processing technique, thereby enhancing food safety.

We appreciate the comment's suggestions for expanding the voluntary submission program, but we note that the expansion suggested by the comment is not within the scope of the revisions to Form FDA 2541e. The paperwork reduction analysis only estimates the additional paperwork burden associated with voluntary submission on Form FDA 2541e of information for food products, limited to those the regulatory classification of which is not obvious when we look at the product and the product label.

(Comment 11) One comment suggested that Form FDA 2541e does not provide the flexibility needed for manufacturers to report their processes. The comment indicated that the draft form only provides ''one size fits all'' mandatory processing parameters by listing limited options for processors to choose from.

(Response) When we revised Form FDA 2541e, we listed all the current processing methods used by industry, and included an ''Other'' choice for many fields to permit manufacturers to report new and emerging methods that may be developed in the future. As a result of these revisions, the form provides the flexibility needed to describe any process. In addition, we issued a draft guidance describing the revised forms and provided interested parties an opportunity to comment on alternative processes that we should include on the forms.

(Comment 12) One comment suggested that a processor should be able to submit one Form FDA 2541e that describes a process for multiple forms of a product (e.g., ''fresh pack pickles (whole, cut or sliced)''), multiple product packing mediums, and multiple product names that indicate minor formulation changes, provided that the preparation of these products follows the identical scheduled process.

(Response) We agree that, under the appropriate circumstances, a processor should be able to submit one paper Form FDA 2541e that describes a process for multiple forms of a product. In the past, a processor could complete Form FDA 2541e in the manner described. The revised paper version of Form FDA 2541e may still be prepared in this manner, provided that the multiple forms of the product all follow the identical scheduled process and other factors (e.g., container type or size) do not make it necessary to submit a separate filing. The paper version of revised Form FDA 2541e will allow a processor to enter (1) multiple product forms (e.g., ''fresh pack pickles (whole, cut or sliced)''), (2) multiple product packing mediums (such as brine, oil, sauce), and (3) multiple product names that indicate minor formulation changes (such as hot, medium, mild salsa).

(Comment 13) One comment stated that we do not need percent headspace information on a process filing for an acidified product and, if the form includes the data element, then we should provide enough room on the

form for a processor to identify multiple percent headspace figures associated with multiple container sizes.

(Response) Information regarding the percent headspace information on a process filing for an acidified product may help us analyze a processing method that uses overpressure. While overpressure typically is used for low acid products that are thermally processed at elevated temperatures, overpressure may also be used for an acidified product. Thus, revised Form FDA 2541e includes a data field for percent headspace. If overpressure is not being used, the correct response is ''N/A.''

We also disagree that we should allow a processor to identify multiple figures associated with multiple container sizes on a single process filing. A process filing may not be submitted for multiple container types or sizes to prevent the detention of product where multiple types or sizes are on one submission and only part of the submission (e.g., one container size and/or type) is questionable from a food safety perspective. A separate Form FDA 2541e is needed for each container type or size. Because a separate Form FDA 2541e is needed for each container type or size, room for multiple entries for headspace associated with multiple container sizes is not necessary.

(Comment 14) One comment suggested that we clarify how to complete the data field, ''What is the vacuum,'' in section C.2 of revised Form FDA 2541e when the processor has a range of values to report.

(Response) We revised the instructions for section C.2 of Form FDA 2541e to clarify that the processor of an acidified food that is vacuum packed should report the minimum value if there is a range of values for the vacuum.

(Comment 15) One comment suggested that we add ''Center Temperature'' as a thermal process mode in section G of revised Form FDA 2541e. The comment described ''Center Temperature'' as a process in which the processor punctures the lid and inserts a thermometer into the container to take a center temperature reading. When the center temperature reaches the appropriate temperature, the processor begins the time count. The comment explained that the center temperature method differs from the other methods because the time count does not begin when the container is filled or the lid is placed on the container but instead begins when the center temperature reaches the specified temperature. In addition, the comment requests that center temperature be added as a choice in the ''Note'' under Section D (Container Size) that references specific thermal processing mode for which the processor may choose to report volume rather than container dimensions.

(Response) We disagree with the comment's suggestion to add ''Center Temperature'' as a thermal process mode in section G and as a choice in the ''Note'' under section D of revised Form FDA 2541e. ''Center temperature'' is not a thermal process mode because it does not include a defined scheduled process. A scheduled process for acidified foods can consist of a minimum of two components as in the case of a ''hot fill and hold'' or as many as three components for products that are processed using one of the other processing modes selected. The term ''center temperature'' or ''center can temperature'' refers to the temperature of the product achieved at the end of the completed scheduled process and not a thermal process mode in and of itself.

(Comment 16) One comment suggested that we clarify where to report the maximum pH value on Form FDA 2541e.

(Response) We no longer request the maximum pH value of the product on draft Form FDA 2541e. We revised the form to refer to the ''finished equilibrium pH'' value of the product for consistency with the use of that term in § 114.80. We revised the instructions for section E.2 of Form FDA 2541e to clarify that the finished equilibrium pH should be reported.

(Comment 17) One comment suggested that we add ''critical to the scheduled process'' to the term ''Microbial Preservative(s)'' in section E.6 of draft Form FDA 2541e. The comment explained that some preservatives are added for purposes other than controlling the growth of microorganisms and should not be part of the scheduled process.

(Response) We revised the title of section E.6 of draft Form FDA 2541e to read ''Microbial Preservative(s) Critical to the Scheduled Process.''

(Comment 18) One comment suggested we clarify that trade associations are an appropriate source for a scheduled process.

(Response) Trade associations may provide the scientific support for a scheduled process. In response to the comment, we have revised our instructions to include a reference to ''organization'' which by definition would include trade associations in the list of examples for the term ''process source.''

(Comment 19) One comment asked us to clarify how to fill out section I on Form FDA 2541e for companies that use center temperature, particularly with respect to columns 1, 2, 3, 5, and 7.

(Response) As discussed in the response to Comment 15, we disagree that ''center temperature'' is a thermal process mode. The term ''center temperature'' or ''center can temperature'' refers to the temperature of the product achieved at the end of the completed scheduled process and not a thermal process mode in and of itself. The center temperature is the end point achieved by the scheduled process and is not the scheduled process itself. The instructions for Form FDA 2541e provide step-by-step directions for how to fill out each section of the form.

(Comment 20) One comment noted that the draft guidance document, ''Acidified and Low-Acid Canned Foods: Draft Guidance: Acidified Foods (September, 2010),'' has not been finalized and suggested that we should refrain from revising the process filing forms until the guidance has become final. The comment expressed concern that the ''Food Product Group'' categories might be affected by possible changes to the draft guidance.

(Response) The draft acidified foods guidance is intended to help commercial food processors in determining whether their food products are subject to the regulations for acidified foods and provides our thinking on several topics related to the processing of, and process filings for, acidified foods. We have prepared a separate draft guidance document that focuses on procedures for submitting the revised process filing forms. The draft guidance entitled ''Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g (Food Process Filing Forms) to FDA in Electronic or Paper Format (January 2014),'' is available on FDA's Web site at *http://www.fda.gov/FoodGuidances.* As discussed in the response to Comment 3, we expect to issue this guidance as final guidance on or about the date that the revised forms become operational. Further, we disagree that the ''Food Product Group'' categories might be affected by possible changes to the draft acidified foods guidance. The ''Food Product Group'' categories correspond to the first two digits of the FDA Product Code and would not be affected by changes to the draft acidified foods guidance.

(Comment 21) One comment suggested that we remove the ''Food Product Groups'' category of ''Dressings/condiments (e.g. salad dressing, chutney, salsa, pepper sauce, etc.)'' from all process filing forms because all

dressings and sauces with a pH of 4.6 or below should be considered acid foods.

(Response) The definition of acidified foods in § 114.3(b) only excludes from the coverage of part 114 those dressing and condiments that are acid foods that contain small amounts of low-acid ingredients and have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food. We included the ''Food Product Group'' category, ''Dressings/condiments (e.g. salad dressing, chutney, salsa, pepper sauce, etc.),'' on the forms to accommodate the possibility that some dressings and condiments may not satisfy these criteria.

(Comment 22) One comment expressed concern that the ''Food Product Group'' categories for various fruit and vegetable juices indicates that FDA considers all fruit and vegetable juices to be subject to the acidified foods regulations and, therefore, will require process filings for all fruit and vegetable juices.

(Response) The definition of acidified foods in § 114.3(b) excludes from the coverage of part 114 those fruit and vegetable juices that meet the definition of 21 CFR 120.1(a) and have a finished natural pH of 4.6 or below. We included ''Food Product Group'' categories for various fruit and vegetable juices on all the forms (forms for low-acid foods as well as forms for acidified foods) to accommodate the possibility that some fruit and vegetable juices may not satisfy these criteria.

(Comment 23) One comment suggested we should eliminate the optional ''Food Product Group'' categories from the process filing forms to make the forms easier to complete.

(Response) Because the ''Food Product Group'' information is optional, a manufacturer or packer that chooses not to provide the information may simply skip that section of the form.

(Comment 24) One comment questioned the value of the optional ''Food Product Group'' category information. Another comment asserted that parts of the revised forms appear to be directed toward generating what it characterized as facility profiles, which it further characterized as extraneous information not relevant to public safety and, thus, unnecessary.

(Response) As discussed in section I of this notice, improperly processed low-acid foods present life-threatening hazards if contaminated with foodborne microorganisms, especially *C. botulinum.* The spores of *C. botulinum* need to be destroyed or inhibited to avoid production of the deadly toxin that causes botulism. This is accomplished with good manufacturing procedures, which must include the use of adequate heat processes or other means of preservation. To protect the public health, our regulations in parts 108, 113, and 114 require registration of food processing establishments, filing of process or other data, and maintenance of processing and production records for acidified foods and thermally processed low-acid foods in hermetically sealed containers. We review the process filings to determine their adequacy to protect public health. In the event of a public health emergency, records are used to pinpoint potentially hazardous foods rapidly and thus limit recall activity to affected lots.

We interpret the comment regarding ''facility profiles'' as objecting to our intent to permit manufacturers to voluntarily self-categorize the product for which they are submitting a process filing as one of several optional ''Food Product Group'' categories. When this optional information about the ''Food Product Group'' category is provided, we will use it to help us understand the nature of the products covered by the process filing as we review the scheduled process described in the filing for adequacy to control microbial contamination to ensure safe manufacturing, processing, and packing procedures. We will also use the ''Food Product Group'' category information, in addition to our general knowledge of the industry and the reports we receive, such as those under §§ 108.25(d) and 108.35(d) regarding instances of potential health-endangering spoilage, process deviation, or contamination with microorganisms, to prioritize which facilities to inspect.

(Comment 25) One comment suggested that, to eliminate confusion, we should use ''import codes'' from the U.S. International Trade Commission to clarify the ''Food Product Group'' categories.

(Response) We disagree that using a coding system such as the ''Harmonized Tariff Schedule of the United States Annotated'', which provides the applicable tariff rates and statistical categories for all merchandise imported into the United States, would eliminate confusion. The ''Food Product Group'' categories identifies to FDA a ''group'' of foods that will help us determine the product submission (such as Baby Food or Soup) and prioritize facilities to inspect from a food safety perspective. The ''Food Product Group'' categories correspond to the first two digits of the FDA Product Code, also referred to as the Product Industry Code. We have been using this coding system for decades, and so we believe that using ''import codes'' rather than our longstanding coding system would not enhance our ability to track and identify potentially adulterated products as well as groups of foods for potential health hazards.

(Comment 26) One comment asserted that we have increased the information being requested by 30 percent and, since this increase should be reflected in the time needed to complete the forms, we underestimated the reporting burden in table 1.

(Response) We disagree that we have increased the information being requested or underestimated the time it takes to complete the paper forms. We updated the paper forms to provide responsive information in the form of check boxes. This responsive information has been reported by industry for decades without being provided as check boxes on the paper forms. Adding these check boxes makes the forms longer, but does not increase the information being requested. Instead, the new forms should reduce the time it takes to complete the process filing because a submitter may check a box rather than prepare and manually enter on the paper form a written description of a process. We note that substantial time may be saved by submitters that use the electronic submission system. The electronic submission system will present only those sections of the form that are relevant to the subject matter of the submission, as determined by the information submitted in response to the initial questions. The system will also minimize the submission of incomplete forms, thus saving time that paper form submitters will spend if it becomes necessary to correct a form and submit it again. Finally, we note that, to the extent that the comment is referring to the optional ''Food Product Group'' categories, we estimate that the information is readily available to a submitter and easily provided by checking a box. In summary, we have not increased or decreased our estimate of the total time necessary to complete the new process filing forms because: (1) We have not increased the required information in a process filing; (2) the new forms should reduce the time it takes to complete the process filing because a submitter may check a box rather than prepare and manually enter on the form a written description of a process; and (3) the ''Food Product Group'' category information is optional, readily available, and provided by checking a box.

(Comment 27) One comment asserted that we underestimated the

number of hours it takes to comply with recordkeeping requirements in parts 108, 113, and 114, as reported in table 2. The comment stated that a canning establishment running a single line operation with one 8-hour shift 5 days a week for 52 weeks each year would conduct manufacturing operations for 2,080 hours each year, and the recordkeeping would occupy 25 percent of the time of one full-time employee, or 520 hours per year, which is greater than our estimate of 250 hours. The comment added that, for a facility operating multiple processing lines and/or multiple shifts per day, the recordkeeping burden would be greater.

(Response) We appreciate the information provided by the comment. Since the information relates the recordkeeping experience of a single line operation, without additional information we do not have a sufficient basis for revising the estimated average number of hours of recordkeeping undertaken by all respondents, across various sizes and types of processing facilities. Accordingly, for the purpose of this information collection request, we are retaining our previous estimate. However, in preparation for the next regular information collection request, we will consult with several establishments of varying sizes and types to obtain additional data on the recordkeeping burdens and reevaluate our estimates. We will then publish the revised estimates for comment and consider additional information submitted in response.

(Comment 28) One comment asked us to consult select companies before finalizing the revised forms, in order to obtain these companies' recommendations regarding the content of the forms, as part of a transparent, collaborative effort.

(Response) Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires us to provide notice and a 60-day comment period before submitting the information collection to OMB. Section 3507(a)(1)(D) of the PRA (44 U.S.C. 3507(a)(1)(D)) requires us to publish a second notice announcing our submission of the Information Collection Request to OMB and providing a 30-day comment period during which interested parties may submit their comments directly to OMB. These processes are open to all interested parties rather than to ''select companies.'' Thus, interested parties had sufficient opportunity to comment.

As discussed in our responses to the comments, we have modified the paper-based versions of the four proposed replacement forms and their instructions. We have also modified the electronic submission system to mirror the paper forms. At this time, these documents are available for review on OMB's Web site as part of the Information Collection Request we submitted to OMB.

Description of Respondents: The respondents to this information collection are commercial processors and packers of acidified foods and thermally processed low-acid foods in hermetically sealed containers.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA form number	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
108.25(c)(1) and 108.35(c)(2); Food canning establishment registration.	2541	645	1	645	0.17 (10 mins.) ...	110
108.25(c)(2); Food process filing for acidified method.	2541e	726	11	7,986	0.33 (20 mins.) ...	2,659
108.35(c)(2); Food process filing for low-acid retorted method.	2541d	336	12	4,032	0.33 (20 mins.) ...	1,343
108.35(c)(2); Food process filing for water activity/formulation control method.	2541f	37	6	222	0.33 (20 mins.) ...	74
108.35(c)(2); Food process filing for low-acid aseptic systems.	2541g	42	22	924	0.75 (45 mins.) ...	693
108.25(d); 108.35(d) and (e); Report of any instance of potential health-endangering spoilage, process deviation, or contamination with microorganisms where any lot of the food has entered distribution in commerce.	N/A	1	1	1	4	4
Total	.....	.....	.....	.....	.....	4,883

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

FDA bases its estimate of the number of respondents in table 1 on registrations, process filings, and reports received over the past 3 years. The hours per response reporting estimates are based on our experience with similar programs and information received from industry. The reporting burden for §§ 108.25(d) and 108.35(d) and (e) is minimal because notification of spoilage, process deviation, or contamination of product in distribution occurs less than once a year. Most firms discover these problems before the product is distributed and, therefore, are not required to report the occurrence. We estimate that we will receive one report annually under §§ 108.25(d) and 108.35(d) and (e). The report is expected to take 4 hours per response, for a total of 4 hours.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
113.100 and 114.100	10,392	1	10,392	250	2,598,000

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

FDA bases its estimate of 10,392 recordkeepers in table 2 on its records of the number of registered firms, excluding firms that were inactive or out of business, yet still registered. To avoid double-counting, we have not included estimates for § 108.25(e), (g), and (h) because they merely cross-reference recordkeeping requirements contained in parts 113 and 114 and have been accounted for in the recordkeeping burden estimate. We estimate that 10,392 firms will expend approximately 250 hours per year to fully satisfy the recordkeeping requirements in parts 108, 113 and 114, for a total of 2,598,000 hours.

Finally, our regulations require that processors mark thermally processed low-acid foods in hermetically sealed containers (§ 113.60(c)) and acidified foods (§ 114.80(b) (21 CFR 114.80(b)) with an identifying code to permit lots to be traced after distribution. We seek OMB approval of the third party disclosure requirements in §§ 113.60(c) and 114.80(b). However, we have not included a separate table to report the estimated burden of these regulations. No burden has been estimated for the third party disclosure requirements in §§ 113.60(c) and 114.80(b) because the coding process is done as a usual and customary part of normal business activities. Coding is a business practice in foods for liability purposes, inventory control, and process control in the event of a problem. Under 5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Dated: August 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1139]

Determination That DRIXORAL (Dexbrompheniramine Maleate; Pseudoephedrine Sulfate) Tablet and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Amy Hopkins, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6223, Silver Spring, MD 20993–0002, 301–796–5418, *Amy.Hopkins@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed.

Application No.	Drug	Applicant
NDA 013483	DRIXORAL (dexbrompheniramine maleate and pseudoephedrine sulfate) Tablet, Extended Release; Oral, 6 milligrams (mg)/120 mg.	MSD Consumer Care Inc., 556 Morris Ave., Summit, NJ 07901.
NDA 014685	AVENTYL (nortriptyline hydrochloride (HCl)) Solution; Oral, Equivalent to (EQ) 10 mg Base/5mL.	Ranbaxy Pharmaceuticals Inc., 600 College Rd. East, Princeton, NJ 08540.