the Executive Order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive Order.

This proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing this proposed priority only upon a reasoned determination that its benefits would justify its costs. In choosing among alternative regulatory approaches, we selected those approaches that would maximize net benefits. Based on the analysis that follows, the Department believes that this proposed priority is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive Orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

The benefits of the Disability and Rehabilitation Research Projects and Centers Program have been well established over the years. Projects similar to one envisioned by the proposed priority have been completed successfully, and the proposed priority would generate new knowledge through research. The new DRRP would generate, disseminate, and promote the use of new information that would improve accessibility of the built environment for individuals with disabilities.

Intergovernmental Review: This program is not subject to Executive Order 12372.

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You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: February 19, 2015.

Kathy Greenlee,

Administrator.

[FR Doc. 2015–03888 Filed 2–24–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0362]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals

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 March 27, 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 0910–0139. 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.

Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals—21 CFR Parts 210 and 211 (OMB Control Number 0910–0139)

Under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351(a)(2)(B)), a drug is adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices (CGMPs) to ensure that such drug meets the requirements of the FD&C Act as to safety, and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

The FDA has the authority under section 701(a) of the FD&C Act (21 U.S.C. 371(a)) to issue regulations for the efficient enforcement of the FD&C Act regarding CGMP procedures for manufacturing, processing, and holding drugs and drug products. The CGMP regulations help ensure that drug products meet the statutory requirements for safety and have their purported or represented identity, strength, quality, and purity characteristics. The information collection requirements in the CGMP regulations provide FDA with the necessary information to perform its duty to protect public health and safety. CGMP requirements establish accountability in the manufacturing and processing of drug products, provide for meaningful FDA inspections, and enable manufacturers to improve the quality of drug products over time. The CGMP recordkeeping requirements also serve preventive and remedial purposes and provide crucial information if it is necessary to recall a drug product.

The general requirements for recordkeeping under part 211 (21 CFR part 211) are set forth in § 211.180. Any production, control, or distribution record associated with a batch and required to be maintained in compliance with part 211 must be retained for at least 1 year after the expiration date of the batch and, for certain over-the-counter (OTC) drugs, 3 years after distribution of the batch (§ 211.180(a)). Records for all components, drug product containers, closures, and labeling are required to be maintained for at least 1 year after the expiration date and 3 years for certain OTC products (§ 211.180(b)).

All part 211 records must be readily available for authorized inspections during the retention period (§ 211.180(c)), and such records may be retained either as original records or as true copies (§ 211.180(d)). In addition, 21 CFR 11.2(a) provides that for records required to be maintained but not submitted to the Agency, persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part, provided that the requirements of this part are met. To the extent this electronic option is used, the burden of maintaining paper records should be substantially reduced, as should any review of such records.

In order to facilitate improvements and corrective actions, records must be maintained so that data can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures (§ 211.180(e)). Written procedures for these evaluations are to be established and include provisions for a review of a representative number of batches and, where applicable, records associated with the batch; provisions for a review of complaints, recalls, returned, or salvaged drug products; and investigations conducted under § 211.192 for each drug product.

The specific recordkeeping requirements provided in table 1 are as follows:

Section 211.34—Consultants advising on the manufacture, processing, packing, or holding of drug products must have sufficient education, training, and experience to advise on the subject for which they are retained. Records must be maintained stating the name, address, and qualifications of any consultants and the type of service they provide.

Section 211.67(c)—Records must be kept of maintenance, cleaning, sanitizing, and inspection as specified in §§ 211.180 and 211.182.

Section 211.68—Appropriate controls must be exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Section 211.68(a)—Records must be maintained of calibration checks, inspections, and computer or related system programs for automatic, mechanical, and electronic equipment.

Section 211.68(b)—All appropriate controls must be exercised over all computers or related systems and control data systems to assure that changes in master production and control records or other records are instituted only by authorized persons.

Section 211.72—Filters for liquid filtration used in the manufacture, processing, or packing of injectable drug products intended for human use must not release fibers into such products.

Section 211.80(d)—Each container or grouping of containers for components or drug product containers or closures must be identified with a distinctive code for each lot in each shipment received. This code must be used in recording the disposition of each lot. Each lot must be appropriately identified as to its status.

Section 211.100(b)—Written production and process control procedures must be followed in the execution of the various production and process control functions and must be documented at the time of performance. Any deviation from the written procedures must be recorded and justified.

Section 211.105(b)—Major equipment must be identified by a distinctive identification number or code that must be recorded in the batch production record to show the specific equipment used in the manufacture of each batch of a drug product. In cases where only one of a particular type of equipment exists in a manufacturing facility, the name of the equipment may be used in lieu of a distinctive identification number or code.

Section 211.122(c)—Records must be maintained for each shipment received of each different labeling and packaging material indicating receipt, examination, or testing.

Section 211.130(e)—Inspection of packaging and labeling facilities must be made immediately before use to assure that all drug products have been removed from previous operations. Inspection must also be made to assure that packaging and labeling materials not suitable for subsequent operations have been removed. Results of inspection must be documented in the batch production records.

Section 211.132(c)—Certain retail packages of OTC drug products must bear a statement that is prominently placed so consumers are alerted to the specific tamper-evident feature of the package. The labeling statement is required to be so placed that it will be unaffected if the tamper-resistant feature of the package is breached or missing. If the tamper-evident feature chosen is one that uses an identifying characteristic, that characteristic is required to be referred to in the labeling statement.

Section 211.132(d)—A request for an exemption from packaging and labeling requirements by a manufacturer or packer is required to be submitted in the

form of a citizen petition under 21 CFR 10.30.

Section 211.137—Requirements regarding product expiration dating and compliance with 21 CFR 201.17.

Section 211.160(a)—The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, must be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit. These requirements must be followed and documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms must be recorded and justified.

Section 211.165(e)—The accuracy, sensitivity, specificity, and reproducibility of test methods employed by a firm must be established and documented. Such validation and documentation may be accomplished in accordance with § 211.194(a)(2).

Section 211.166—Stability testing program for drug products.

Section 211.173—Animals used in testing components, in-process materials, or drug products for compliance with established specifications must be maintained and controlled in a manner that assures their suitability for their intended use. They must be identified, and adequate records must be maintained showing the history of their use.

Section 211.180(e)—Written records required by part 211 must be maintained so that data can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures. Written procedures must be established and followed for such evaluations and must include provisions for a representative number of batches, whether approved or unapproved or rejected, and a review of complaints, recalls, returned, or salvaged drug products, and investigations conducted under § 211.192 for each drug product.

Section 211.180(f)—Procedures must be established to assure that the responsible officials of the firm, if they are not personally involved in or immediately aware of such actions, are notified in writing of any investigations, conducted under § 211.198, 211.204, or 211.208, any recalls, reports of inspectional observations issued, or any regulatory actions relating to good manufacturing practices brought by FDA.

Section 211.182—Specifies requirements for equipment cleaning records and the use log.

Section 211.184—Specifies requirements for component, drug product container, closure, and labeling records.

Section 211.186—Specifies master production and control records requirements.

Section 211.188—Specifies batch production and control records requirement.

Section 211.192—Specifies the information that must be maintained on the investigation of discrepancies found in the review of all drug product production and control records by the quality control staff.

Section 211.194—Explains and describes laboratory records that must be retained.

Section 211.196—Specifies the information that must be included in records on the distribution of the drug.

Section 211.198—Specifies and describes the handling of all complaint files received by the applicant.

Section 211.204—Specifies that records be maintained of returned and salvaged drug products and describes the procedures involved.

Written procedures, referred to here as standard operating procedures (SOPs), are required for many part 211 records. The current SOP requirements were initially provided in a final rule published in the **Federal Register** of September 29, 1978 (43 FR 45014), and are now an integral and familiar part of the drug manufacturing process. The major information collection impact of SOPs results from their creation. Thereafter, SOPs need to be periodically updated. A combined estimate for routine maintenance of SOPs is provided in table 1. The 25 SOP provisions under part 211 in the combined maintenance estimate include:

Section 211.22(d)—Responsibilities and procedures of the quality control unit;

Section 211.56(b)—Sanitation procedures;

Section 211.56(c)—Use of suitable rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents;

Section 211.67(b)—Cleaning and maintenance of equipment;

Section 211.68(a)—Proper performance of automatic, mechanical, and electronic equipment;

Section 211.80(a)—Receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers or closures;

Section 211.94(d)—Standards or specifications, methods of testing, and methods of cleaning, sterilizing, and processing to remove pyrogenic properties for drug product containers and closures;

Section 211.100(a)—Production and process control;

Section 211.110(a)—Sampling and testing of in-process materials and drug products;

Section 211.113(a)—Prevention of objectionable microorganisms in drug products not required to be sterile;

Section 211.113(b)—Prevention of microbiological contamination of drug products purporting to be sterile, including validation of any sterilization process;

Section 211.115(a)—System for reprocessing batches that do not conform to standards or specifications, to insure that reprocessed batches conform with all established standards, specifications, and characteristics;

Section 211.122(a)—Receipt, identification, storage, handling, sampling, examination and/or testing of labeling and packaging materials;

Section 211.125(f)—Control procedures for the issuance of labeling;

Section 211.130—Packaging and label operations, prevention of mixup and cross contamination, identification and handling of filed drug product containers that are set aside and held in unlabeled condition, and identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch;

Section 211.142—Warehousing;

Section 211.150—Distribution of drug products;

Section 211.160—Laboratory controls;

Section 211.165(c)—Testing and release for distribution;

Section 211.166(a)—Stability testing;

Section 211.167—Special testing requirements;

Section 211.180(f)—Notification of responsible officials of investigations, recalls, reports of inspectional observations, and any regulatory actions relating to good manufacturing practice;

Section 211.198(a)—Written and oral complaint procedures, including quality control unit review of any complaint involving specifications failures, and serious and unexpected adverse drug experiences;

Section 211.204—Holding, testing, and reprocessing of returned drug products; and

Section 211.208—Drug product salvaging.

In addition, the following regulations in parts 610 and 680 (21 CFR parts 610

and 680) reference certain CGMP regulations in part 211: §§ 610.12(g), 610.13(a)(2), 610.18(d), 680.2(f), and 680.3(f). In table 1, the burden associated with the information collection requirements in these regulations is included in the burden estimates under §§ 211.165, 211.167, 211.188, and 211.194, as appropriate.

Although most of the CGMP provisions covered in this document were created many years ago, there will be some existing firms expanding into new manufacturing areas and startup firms that will need to create SOPs. As provided in table 1, FDA is assuming that approximately 100 firms will have to create up to 25 SOPs for a total of 2,500 records, and the Agency estimates that it will take 20 hours per recordkeeper to create 25 new SOPs for a total of 50,000 hours.

In the **Federal Register** of November 10, 2014 (79 FR 66724), 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 RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
SOP Maintenance	4,360	1	4,360	25	109,000
New startup SOPs	100	25	2500	20	50,000
211.34—Consultants	4,360	.25	1,090	.5 (30 minutes)	545
211.67(c)—Equipment cleaning and maintenance.	4,360	50	218,000	.25 (15 minutes)	54,500
211.68—Changes in master production and control records or other records.	4,360	2	8,720	1	8,720
211.68(a)—Automatic, mechanical, and electronic equipment.	4,360	10	43,600	.5 (30 minutes)	21,800
211.68(b)—Computer or related systems.	4,360	5	21,800	.25 (15 minutes)	5,450
211.72—Filters	4,360	.25	1,090	1	1,090
211.80(d)—Components and drug product containers or closures.	4,360	.25	1,090	.10 (6 minutes)	109
211.100(b)—Production and process controls.	4,360	3	13,080	2	26,160
211.105(b)—Equipment identification.	4,360	.25	1,090	.25 (15 minutes)	273
211.122(c)—Labeling and packaging material.	4,360	50	218,000	.25 (15 minutes)	54,500
211.130(e)—Labeling and packaging facilities.	4,360	50	218,000	.25 (15 minutes)	54,500
211.132(c)—Tamper-evident packaging.	1,769	20	35,380	.5 (30 minutes)	17,690
211.132(d)—Tamper-evident packaging.	1,769	.2	354	.5 (30 minutes)	177
211.137—Expiration dating	4,360	5	21,800	.5 (30 minutes)	10,900
211.160(a)—Laboratory controls.	4,360	2	8,720	1	8,720
211.165(e)—Test methodology	4,360	1	4,360	1	4,360
211.166—Stability testing	4,360	2	8,720	.5 (30 minutes)	4,360
211.173—Laboratory animals	1,077	1	1,077	.25 (15 minutes)	269
211.180(e)—Production, control, and distribution records.	4,360	.2	872	.25 (15 minutes)	218
211.180(f)—Procedures for notification of regulatory actions.	4,360	.2	872	1	872
211.182—Equipment cleaning and use log.	4,360	2	8,720	.25 (15 minutes)	2,180
211.184—Component, drug product container, closure, and labeling records.	4,360	3	13,080	.5 (30 minutes)	6,540
211.186—Master production and control records.	4,360	10	43,600	2	87,200
211.188—Batch production and control records.	4,360	25	109,000	2	218,000
211.192—Discrepancies in drug product production and control records.	4,360	2	8,720	1	8,720
211.194—Laboratory records	4,360	25	109,000	.5 (30 minutes)	54,500
211.196—Distribution records	4,360	25	109,000	.25 (15 minutes)	27,250
211.198—Compliant files	4,360	5	21,800	1	21,800
211.204—Returned drug products.	4,360	10	43,600	.5 (30 minutes)	21,800

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Total					882,203

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

Dated: February 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03881 Filed 2–24–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0878]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification for a New Dietary Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 (the PRA).

DATES: Fax written comments on the collection of information by March 27, 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 0910–0330. 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.

Premarket Notification for a New Dietary Ingredient—21 CFR 190.6 (OMB Control Number 0910–0330)—Extension

Section 413(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350b(a)) provides that at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient, the manufacturer or distributor of the dietary supplement or of the new dietary ingredient is to submit to us (as delegate for the Secretary of Health and Human Services) information upon which the manufacturer or distributor has based its conclusion that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe. FDA's implementing regulation, 21 CFR 190.6, requires this information to be submitted to the Office of Nutrition, Labeling, and Dietary Supplements (ONLDS) in the form of a notification. Under § 190.6(b), the notification must include the following: (1) The name and complete address of the manufacturer or distributor, (2) the name of the new dietary ingredient, (3) a description of the dietary supplement(s) that contain the new dietary ingredient, including the level of the new dietary ingredient in the dietary supplement and the dietary supplement's conditions of use, (4) the history of use or other evidence of safety establishing that the new dietary ingredient will reasonably be expected to be safe when used under the conditions recommended or suggested in the labeling of the dietary supplement, and (5) the signature of a responsible person designated by the manufacturer or distributor.

These premarket notification requirements are designed to enable us to monitor the introduction into the marketplace of new dietary ingredients and dietary supplements that contain new dietary ingredients, in order to protect consumers from ingredients and products whose safety is unknown. We use the information collected in new dietary ingredient notifications to evaluate the safety of new dietary ingredients in dietary supplements and to support regulatory action against ingredients and products that are potentially unsafe.

We are developing an electronic portal that interested persons will be able to use to electronically submit their notifications to ONLDS via FDA Unified Registration and Listing System (FURLS). Firms that prefer to submit a paper notification in a format of their own choosing will still have the option to do so, however. Form FDA 3880 prompts a submitter to input the elements of a new dietary ingredient notification (NDIN) in a standard format and helps the submitter organize its NDIN to focus on the information needed for our safety review. Safety information will be submitted via a supplemental form entitled ''New Dietary Ingredient (NDI) Safety Information.'' This form provides a standard format to describe the history of use or other evidence of safety on which the manufacturer or distributor bases its conclusion that the new dietary ingredient will be reasonably expected to be safe under the conditions of use recommended or suggested in the labeling of the dietary supplement, as well as related identity information that is necessary to demonstrate safety by showing that the new dietary ingredient and dietary supplement(s) that are the subject of the notification are the same or similar to the ingredients and products for which safety data and information have been provided. Draft screenshots of Form FDA 3880 and the supplemental safety information form are available for comment at *http://www.fda.gov/Food/DietarySupplements/NewDietaryIngredientsNotificationProcess/ucm356620.htm.*

Description of Respondents: The respondents to this collection of information are manufacturers and distributors in the dietary supplement industry; specifically, firms that manufacture or distribute new dietary ingredients or dietary supplements that contain a new dietary ingredient.

In the **Federal Register** of November 14, 2014 (79 FR 68275), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. We received three comments in response to the notice. Two of the comments were unrelated to the PRA, and therefore we did not consider them.