

## ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Council on Developmental Disabilities Program Performance Report ..	55	1	138	7,590

*Estimated Total Annual Burden Hours: 7,590.*

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. *E-mail address:* [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**

*Reports Clearance Officer.*

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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 October 28, 2011.

**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 e-mailed to [oira\\_submission@omb.eop.gov](mailto: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:

Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, [juanmanuel.vilela@fda.hhs.gov](mailto:juanmanuel.vilela@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—21CFR Parts 210 and 211 (OMB Control No. 0910-0139)—Extension

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 one year after the expiration date of the batch and, for certain OTC drugs, three 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 one year after the expiration date and three 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 of this document 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 are set forth.

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(c)—Homeopathic drug product requirements are set forth.

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 of this document. 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(h), 610.13(a)(2), 610.18(d), 680.2(f), and 680.3(f). In table 1 of this document, 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 of this document, 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 May 31, 2011 (76 FR 31342), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment that pertained to the information collection.

The comment, from a plasma protein therapies association, stated that data from their association members may be higher than FDA's estimates and provided some examples of differences between their numbers and FDA's estimates. The comment stated that table 1 in the notice provides averages, but does not give data range. The comment requested that FDA provide data ranges so they could better assess if their members' high data are factored into the Agency's averages.

The burden estimates in the 60-day notice were compiled by FDA personnel (including field personnel who visit sites and review records) familiar with the records and the time it takes to assemble and maintain these records. The estimates are not expressed in ranges of data. The burden estimates are published every 3 years in the **Federal Register** to give the public an opportunity to comment on the accuracy of the estimates. We appreciate that the comment informed us that their actual data differed from our estimates. However, for us to consider revising our estimates, we request that the comment

provide to the docket specific proposals for their members for the CFR sections on what the burden estimates should be and headings in table 1 of this notice.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours) <sup>2</sup>	Total hours
SOP maintenance (See list of 25 SOPs in the <b>SUPPLEMENTARY INFORMATION</b> section of this document)	4,184	1	4,184	25	104,600
New startup SOPs .....	100	25	2,500	20	50,000
211.34 .....	4,184	.25	1,046	30/60	523
211.67(c) .....	4,184	50	209,200	15/60	52,300
211.68 .....	4,184	2	8,368	1	8,368
211.68(a) .....	4,184	10	41,840	30/60	20,920
211.68(b) .....	4,184	5	20,920	15/60	5,230
211.72 .....	4,184	.25	1,046	1	1,046
211.80(d) .....	4,184	.25	1,046	6/60	105
211.100(b) .....	4,184	3	12,552	2	25,104
211.105(b) .....	4,184	.25	1,046	15/60	262
211.122(c) .....	4,184	50	209,200	15/60	52,300
211.130(e) .....	4,184	50	209,200	15/60	52,300
211.132(c) .....	1,698	20	33,960	30/60	16,980
211.132(d) .....	1,698	.2	340	30/60	170
211.137 .....	4,184	5	20,920	30/60	10,460
211.160(a) .....	4,184	2	8,368	1	8,368
211.165(e) .....	4,184	1	4,184	1	4,184
211.166(c) .....	4,184	2	8,368	30/60	4,184
211.173 .....	1,077	1	1,077	15/60	269
211.180(e) .....	4,184	.2	837	15/60	209
211.180(f) .....	4,184	.2	837	1	837
211.182 .....	4,184	2	8,368	15/60	2,092
211.184 .....	4,184	3	12,552	30/60	6,276
211.186 .....	4,184	10	41,840	2	83,680
211.188 .....	4,184	25	104,600	2	209,200
211.192 .....	4,184	2	8,368	1	8,368
211.194 .....	4,184	25	104,600	30/60	52,300
211.196 .....	4,184	25	104,600	15/60	26,150
211.198 .....	4,184	5	20,920	1	20,920
211.204 .....	4,184	10	41,840	30/60	20,920
Total .....					848,625

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format “[number of minutes per response]/60”.

Dated: September 22, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-D-0212]

#### Draft Guidance for Industry: Applications for Premarket Review of New Tobacco Products; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Applications for Premarket Review of New Tobacco Products.” The draft guidance is intended to assist persons submitting applications for new tobacco products under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). The draft guidance explains, among other things, for new tobacco product applications, who submits, when and how to submit, what information the FD&C Act requires applicants to submit, and what information FDA recommends that applicants submit.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft

guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by December 27, 2011.

**ADDRESSES:** Submit electronic comments on the draft guidance, including comments on the proposed collection of information, to <http://www.regulations.gov>.

Submit written comments on the draft guidance, including comments regarding the proposed collection of information, to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance document entitled “Applications for Premarket Review of New Tobacco Products” to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229. Send one self-addressed adhesive