DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0362]

Agency Information Collection Activities; Proposed Collection; 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 or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection for the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals.

DATES: Submit either electronic or written comments on the collection of information by February 12, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 12, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of February 12, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2011–N–0362 for ''Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

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

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

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

Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals (21 CFR Parts 210 and 211)

OMB Control Number 0910–0139—Extension

This information collection supports FDA regulations. Specifically, 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 Practice (CGMP). The CGMP regulations help ensure 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 for manufacturing and processing 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)). Additionally, § 11.2(a) (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.

To facilitate improvements and corrective actions, records must be maintained so data can be used to evaluate the quality standards of each drug product on at least an annual basis and determine whether to change any 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 information collection provisions 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. 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 CGMP provisions covered in this document were created many years ago, some existing firms expanding into new manufacturing areas and startup firms will need to create SOPs. As provided in table 1, FDA assumes approximately 50 firms will have to create up to 25 SOPs for a total of 1,250 records, estimating 20 hours per recordkeeper to create 25 new SOPs for a total of 25,000 hours.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours) [1]	Total hours
SOP Maintenance	3,270		3,270	25	81,750
New Startup SOPs	50	25	1,250	20	25,000
211.34—Consultants	3,270	0.25	818	5	4090
211.67(c)—Equipment cleaning and maintenance	3,270	50	163,500	0.25	40,875
211.68—Changes in master production and control records or other records	3,270	2	6,540	1	6,540
211.68(a)—Automatic, mechanical, and electronic equipment	3,270	10	32,700	0.5	16,350
211.68(b)—Computer or related systems	3,270	5	16,350	0.25	4,088
211.72—Filters	416	0.25	104	1	104
211.80(d)—Components and drug product containers or closures	3,270	0.25	818	0.1	82
211.100(b)—Production and process controls	3,270	3	9,810	2	19,620
211.105(b)—Equipment identification	3,270	0.25	818	0.25	205
211.122(c)—Labeling and packaging material	3,270	50	163,500	0.25	40,875
211.130(e)—Labeling and packaging facilities	3,270	50	163,500	0.25	40,875
211.132(c)—Tamper-evident packaging	1,613	20	32,260	0.5	16,130
211.132(d)—Tamper-evident packaging	1,613	0.2	323	0.5	162
211.137—Expiration dating	3,270	5	16,350	0.5	8,175
211.160(a)—Laboratory controls	3,270	2	6,540	1	6,540
211.165(e)—Test methodology	3,270	1	3,270	1	3,270
211.166—Stability testing	3,270	2	6,540	0.5	3,270
211.173—Laboratory animals	33	1	33	0.25	8
211.180(e)—Production, control, and distribution records	3,270	0.2	654	0.25	164
211.180(f)—Procedures for notification of regulatory actions	3,270	0.2	654	1	654
211.182—Equipment cleaning and use log	3,270	2	6,540	0.25	1,635
211.184—Component, drug product container, closure, and labeling records	3,270	3	9,810	0.5	4,905
211.186—Master production and control records	3,270	10	32,700	2	65,400
211.188—Batch production and control records	3,270	25	81,750	2	163,500
211.192—Discrepancies in drug product production and control records	3,270	2	6,540	1	6,540
211.194—Laboratory records	3,270	25	81,750	0.5	40,875
211.196—Distribution records	3,270	25	81,750	0.25	20,438
211.198—Compliant files	3,270	5	16,350	1	16,350
211.204—Returned drug products	3,270	10	32,700	0.5	16,350
Total					651,139

[1] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format ''[number of minutes per response]/60''.

The recordkeeping requirement estimates provided in table 2 are specific to medical gases. In particular, on June 29, 2017, FDA published a Notice of Availability (NOA) in the **Federal Register** regarding revised draft guidance for industry entitled ''Current Good Manufacturing Practice for Medical Gases'' (82 FR 29565). This guidance is intended to help medical gas manufacturers comply with applicable CGMP regulations found in parts 210 and 211. In the NOA for the revised draft guidance, FDA noted the guidance includes information collection provisions subject to review by the OMB under the PRA and, in accordance with the PRA, before publication of the final guidance, FDA intends to solicit public comment and obtain OMB approval for any recommended new information collections or material modifications to previously approved collections of information found in FDA regulations. This notice is intended to solicit such public comment.

The regulations addressed in table 2 are the same as those listed in table 1, but the estimated information collection burden differs and is specific to medical gas manufacturing. FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN (MEDICAL GASES) [1]

21 CFR section/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours) [1]	Total hours
SOP Maintenance	2,284	0.65	1,485	25	37,125
New startup SOPs	100	25	2,500	20	50,000
211.34—Consultants	2,284	0.25	571	0.5	286
211.67(c)—Equipment cleaning and maintenance	2,284	32.5	74,230	0.25	18,558
211.68—Changes in master production and control records or other records	2,284	2	4,568	1	4,568
211.68(a)—Automatic, mechanical, and electronic equipment	2,284	10	22,840	0.5	11,420
211.68(b)—Computer or related systems	2,284	5	11,420	0.25	2,855
211.72—Filters	2,284	0.25	571	1	571
211.80(d)—Components and drug product containers or closures	2,284	0.25	571	0.1	57
211.100(b)—Production and process controls	2,284	3	6,382	2	13,704
211.105(b)—Equipment identification	2,284	0.25	571	0.25	143
211.122(c)—Labeling and packaging material	2,284	50	114,200	0.25	28,550
211.130(e)—Labeling and packaging facilities	2,284	50	114,200	0.25	28,550
211.132(c)—Tamper-evident packaging	2,284	20	45,680	0.5	22,840
211.132(d)—Tamper-evident packaging	2,284	0.2	457	0.5	229
211.137—Expiration dating	2,284	3.25	7,423	0.33	2,450
211.160(a)—Laboratory controls	2,284	2	4,568	1	4,568
211.165(e)—Test methodology	2,284	1	2,284	1	2,284
211.166—Stability testing	2,284	1.3	2,969	0.33	980
211.173—Laboratory animals	2,284	1	2,284	0.25	571
211.180(e)—Production, control, and distribution records	2,284	0.2	457	0.25	114
211.180(f)—Procedures for notification of regulatory actions	2,284	0.2	457	1	457
211.182—Equipment cleaning and use log	2,284	1.3	2,969	0.16	475
211.184—Component, drug product container, closure, and labeling records	2,284	1.95	4,454	0.33	1,470
211.186—Master production and control records	2,284	10	22,840	2	45,680
211.188—Batch production and control records	2,284	16.25	37,115	1.3	48,250
211.192—Discrepancies in drug product production and control records	2,284	2	4,568	1	4,568
211.194—Laboratory records	2,284	25	57,100	0.5	28,550
211.196—Distribution records	2,284	25	57,100	0.25	14,275
211.198—Complaint files	2,284	5	11,420	1	11,420
211.204—Returned drug products	2,284	10	22,840	0.5	11,420
Total					396,988

[1] 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: December 8, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26932 Filed 12–13–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4562]

Public Workshop on Safety Assessment for Investigational New Drug Safety Reporting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Safety Assessment for Investigational New Drug Safety Reporting; Public Workshop'' that appeared in the **Federal Register** of November 27, 2017. The document announced a public workshop to engage external stakeholders in discussions related to finalizing the draft guidance entitled ''Safety Assessment for IND Safety Reporting.'' The date of the meeting has changed.

FOR FURTHER INFORMATION CONTACT: Lauren Wedlake, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6362, Silver Spring, MD 20993, 301–796–2728, *Lauren.Wedlake@fda.hhs.gov.*

In the **Federal Register** of Monday, November 27, 2017, in FR Doc. 2017–25454, the following correction is made:

1. On page 56036, in the first column, in the first sentence of the **DATES** section, ''The public workshop will be held on January 11, 2018, from 9 a.m. to 4 p.m., Eastern Time.'' is corrected to read ''The public workshop will be held on March 8, 2018, from 9 a.m. to 4 p.m., Eastern Time.''

Dated: December 8, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26938 Filed 12–13–17; 8:45 am]

BILLING CODE 4164–01–P