program payments for IME and GME are based upon an accurate number of FTE–IRs, determined in accordance with Medicare regulations. The IR data submitted by the hospitals are used by the FIs/MACs during their audits of the providers' cost reports. The audit procedures help assure that the information reported was correct, and that IRs who should not have been reported by the hospitals (or portions of the IRs' time) are not included in the FTE count. The FIs/MACs also use reports of duplicate IRs to prevent improper payment for IME and GME. *Form Number:* CMS–R–64 (OMB#: 0938–0456); *Frequency:* Reporting—Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 1,190; *Total Annual Responses:* 1,190; *Total Annual Hours:* 2,380. (For policy questions regarding this collection contact Milton Jacobson at 410–786–7553. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on 410–786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *February 8, 2010.*

OMB, Office of Information and Regulatory Affairs. Attention: CMS Desk Officer. *Fax Number:* 202–395–6974. *E-mail: OIRA_submission@omb.eop.gov.*

Dated: December 24, 2009.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E9–31299 Filed 1–7–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–906]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* The Fiscal Soundness Reporting Requirements; *Use:* CMS is assigned responsibility for overseeing all Medicare Advantage Organizations (MAO), Prescription Drug Plan (PDP) sponsors, 1876 Cost Plans, Demonstration Plans and PACE organizations on-going financial performance. Specifically, CMS needs the requested collection of information to establish that contracting entities within those programs maintain fiscally sound organizations. Refer to the supporting documents for a list of changes to this collection. *Form Number:* CMS–906 (OMB#: 0938–0469); *Frequency:* Reporting—Yearly and Quarterly; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 514; *Total Annual Responses:* 1039; *Total Annual Hours:* 346. (For policy questions regarding this collection contact Robert Ahern at 410–786–0073. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *March 9, 2010:*

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: December 24, 2009.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E9–31301 Filed 1–7–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0568]

Draft Guidance for Industry on Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products; Availability

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 "Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products." The draft guidance encourages manufacturers of medically necessary drug products (MNPs) and components to develop contingency production plans in the event of an emergency that results in high absenteeism at one or more production

facilities. The purpose of the draft guidance is to provide to industry considerations for developing such emergency plans, as well as to discuss the Center for Drug Evaluation and Research's (CDER's) intended approach to assist in avoiding drug product shortages that may have a negative impact on the national public health during such emergencies.

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 March 9, 2010. Submit written comments on the proposed collection of information by March 9, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Thomas Christl, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., WO Bldg. 51, rm. 3359, Silver Spring, MD 20993, 301–796–2057.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products." The draft guidance encourages manufacturers of medically necessary drug products (MNPs) and components to develop contingency production plans in the event of an emergency that results in high absenteeism at one or more production facilities. In particular, the draft guidance provides recommendations regarding considerations for the development and implementation of a contingency production plan, including specific elements to include in such a plan. The draft guidance is intended for manufacturers of finished drug products as well as manufacturers of the raw materials necessary for manufacturing an MNP.

The purpose of this draft guidance is to provide to industry considerations for developing emergency plans, as well as to discuss CDER's intended approach to assist in avoiding shortages that may have a negative impact on the national public health during such emergencies. This draft guidance applies to manufacturers of drug and therapeutic biologic products regulated by CDER, and any components of those products. These considerations include, but are not limited to:

- General preparedness through employee education and immunization,
- Prioritization of manufactured products based on medical necessity,
- Developing training, manufacturing and laboratory contingencies for high absenteeism, and
- How to plan for returning to normal operations.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 that 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 before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, FDA invites comments on these topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The draft guidance recommends that manufacturers of drug and therapeutic biological products and manufacturers of raw materials and components used in those products develop a written Emergency Plan (Plan) for maintaining an adequate supply of MNPs during an emergency that results in high employee absenteeism. The draft guidance discusses the issues that should be covered by the Plan, such as: (1) Identifying a person or position title (as well as two designated alternates) with the authority to activate and deactivate the Plan and make decisions during the emergency; (2) prioritizing the manufacturer's drug products based on medical necessity; (3) identifying actions that should be taken prior to an anticipated period of high absenteeism; (4) identifying criteria for activating the Plan; (5) performing quality risk assessments to determine which manufacturing activities may be reduced to enable the company to meet a demand for MNPs; (6) returning to normal operations and conducting a post-execution assessment of the execution outcomes; and (7) testing the Plan. The draft guidance recommends developing a Plan for each individual manufacturing facility as well as a broader Plan that addresses multiple sites within the organization (for purposes of this analysis, we consider the Plan for an individual manufacturing facility as well as the broader Plan to comprise one Plan for each manufacturer). Based on CDER's

data on the number of manufacturers that would be covered by the draft guidance, we estimate that approximately 70 manufacturers will develop an Emergency Plan as recommended by the draft guidance (i.e., 1 Plan per manufacturer to include all manufacturing facilities, sites, and drug products), and that each Plan will take approximately 500 hours to develop, maintain, and update.

The draft guidance also encourages manufacturers to include a procedure in their Plan for notifying CDER when the Plan is activated and when returning to normal operations. The draft guidance recommends that these notifications occur within 1 day of a Plan's activation and within 1 day of a Plan's deactivation. The draft guidance specifies the information that should be included in these notifications, such as which drug products will be manufactured under altered procedures, which products will have manufacturing temporarily delayed, and any anticipated or potential drug shortages. We expect that approximately two notifications (for purposes of this analysis, we consider an activation and a deactivation notification to equal one notification) will be sent to CDER by approximately two manufacturers each year, and that each notification will take approximately 16 hours to prepare and submit.

This draft guidance also refers to previously approved collections of information found in FDA regulations. Under the draft guidance, if a manufacturer obtains information after releasing a MNP under its Plan leading to suspicion that the product might be defective, CDER should be contacted immediately (*drugshortages@fda.hhs.gov*) in adherence to existing recall reporting regulations (21 CFR 7.40) (OMB control number 0910–0249) or defect reporting requirements for drug application products (21 CFR 314.81(b)(1)) and therapeutic biological products regulated by CDER (21 CFR 600.14) (OMB control numbers 0910–0001 and 0910–0458, respectively).

The following collections of information found in FDA current good manufacturing practice (CGMP) regulations in part 211 (21 CFR part 211) are approved under OMB control number 0190–0139. The draft guidance encourages manufacturers to maintain records, in accordance with the CGMP requirements (see, e.g., § 211.180), that support decisions to carry out changes to approved procedures for manufacturing and release of products under the Plan. The draft guidance states: A Plan should be developed, written, reviewed, and approved within the site's change control quality system in accordance with the requirements in §§ 211.100(a) and 211.160(a); execution of the Plan should be documented in accordance with the requirements described in § 211.100(b); and standard operating procedures should be reviewed and revised or supplementary procedures developed and approved to enable execution of the Plan.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	Number of Respondents	Number of Responses per Respondent	Total Responses	Hours per Response	Total Hours
Notify FDA of Plan activation and deactivation	2	1	2	16	32
Total					32

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

TABLE 2.—ESTIMATED RECORDKEEPING BURDEN[1]

	Number of Recordkeepers	Number of Records per Recordkeeping	Total Records	Hours per Record	Total Hours
Develop initial Plan	70	1	70	500	35,000
Total					35,000

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

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: January 4, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–87 Filed 1–7–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Injury Prevention and Control, (BSC, NCIPC)

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces, the following meeting of the aforementioned committee:

Time and Date: 8:30 a.m.–5:30 p.m., January 22, 2010.

Place: CDC, 4770 Buford Hwy., NE., Building 106, First Floor, Rooms 1B, Atlanta, Georgia 30341.

Status: Open: 8:30 a.m.–11:30 a.m., January 22, 2010. Closed: 11:30 a.m.–5:30 p.m., January 22, 2010.

Purpose: The board makes recommendations regarding policies, strategies, objectives, and priorities, and reviews progress toward injury prevention goals and provides evidence in injury prevention-related research and programs. The board provides advice on the appropriate balance of intramural and extramural research, and provides advice on the structure, progress and performance of intramural programs. The Board of Scientific Counselors is also designed to provide guidance on extramural scientific program matters, including the: (1) Review of extramural research concepts for funding