under section 402 demonstration waiver authority. The information to be obtained as part of the application form is necessary to document basic information for physician practices that intend to participate in this demonstration initiative. *Form Number:* CMS–10165 (OMB#: 0938–0965); *Frequency: Once; Affected Public:* Private sector—Business or other for-profit; *Number of Respondents:* 2400; *Total Annual Responses:* 2400; *Total Annual Hours:* 520.

3. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* State Plan Pre-print for Integrated Medicare and Medicaid Programs; *Use:* Information submitted via the State Plan Amendment (SPA) pre-print will be used by CMS Central and Regional Offices to analyze a State's proposal to implement integrated Medicare and Medicaid programs. The pre-print is an optional document for use by States to highlight the arrangements between a State and Medicare Advantage Special Needs Plans that are also providing Medicaid services. State Medicaid Agencies will complete the SPA pre-print and submit it to CMS for a comprehensive analysis. The pre-print provides the opportunity for States to confirm that their integrated care model complies with both Federal statutory and regulatory requirements. The pre-print contains assurances, check-off items, and areas for States to describe policies and procedures for subjects such as enrollment, marketing and quality assurance. Based on comments received during the 60-day comment period, both the instructions and pre-print have been revised. *Form Numbers:* CMS–10251 (OMB#: 0938–NEW); *Frequency:* Reporting—Once; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 30; *Total Annual Hours:* 600.

4. *Type of Information Collection Request:* Extension of currently approved collection; *Title of Information Collection:* Information Collection Requirements Contained in 45 CFR Part 162; HIPAA Standards for Electronic Transactions; *Use:* This submission contains information collection requirements in HCFA–0149–F, CMS–0003–P, CMS–0005–P, and CMS–003/005–F. This collection establishes standards for electronic transactions and for code sets to be used in those transactions. The collection standardizes the approximately 400 formats of electronic health care claims used in the United States. The use of these standards significantly reduces the administrative burden associated with paper documents, lowers operating costs, and improves data quality for health care providers and health plans; *Form Number:* CMS–R–218 (OMB# 0938–0866); *Frequency:* On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 3,400,000; *Total Annual Responses:* 3,400,000; *Total Annual Hours:* 1.

5. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Certificate of Destruction for Data Acquired from the Centers for Medicare and Medicaid Services; *Use:* The Certificate of Destruction will be used by recipients of CMS data to certify that they have destroyed the data they have received through a CMS Data Use Agreement (DUA). The DUA requires the destruction of the data at the completion of the project/expiration of the DUA. The DUA addresses the conditions under which CMS will disclose and the User will maintain CMS data that are protected by the Privacy Act of 1974, § 552a and the Health Insurance Portability Accountability Act of 1996. CMS has developed policies and procedures for such disclosures that are based on the Privacy Act and the Health Insurance Portability Act (HIPAA). The Certificate of Destruction is required to close out the DUA and to ensure the data are destroyed and not used for another purpose. *Form Number:* CMS–10252 (OMB# 0938-New); *Frequency:* On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 84.

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 *March 17, 2008.*

OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Dated: February 8, 2008.

Michelle Shortt,

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

[FR Doc. E8–2804 Filed 2–14–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–267]

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:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Advantage Program Requirements Referenced in 42 CFR part 422; *Use:* The information collection requirements are mandated by 42 CFR part 422. Section 4001 of the Balanced Budget Act of 1997 (BBA) added sections 1851 through 1859 to the Social Security Act to establish this program. The Medicare, Medicaid, and SCHIP Benefits Improvement Act and Protection Act of 2000, also added new requirements in addition to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

Medicare Advantage (MA) organizations (formerly M+C organizations) and potential MA organizations (applicants) use the information discussed to comply with the eligibility requirements and the MA

contract requirements. CMS will use this information to approve contract applications, monitor compliance with contract requirements, make proper payment to MA organizations, determine compliance with the new prescription drug benefit requirements established by the MMA, and to ensure that correct information is disclosed to Medicare beneficiaries, both potential enrollees and enrollees. *Form Number:* CMS–R–267 (OMB #0938–0753); *Frequency:* Yearly; *Affected Public:* Business or other for-profit, and individuals or households; *Number of Respondents:* 9,000,670; *Total Annual Responses:* 9,000,670; *Total Annual Hours:* 7,711,085.

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.

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 *April 15, 2008*:

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: February 8, 2008.

Michelle Shortt,

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

[FR Doc. E8–2813 Filed 2–14–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0077]

Agency Information Collection Activities; Proposed Collection; Comment Request; MedWatch: The Food and Drug Administration Medical Products Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the 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 present MedWatch Forms 3500 and 3500A (also known as MedWatch reporting forms) having an OMB expiration date of October 31, 2008. These forms are presently used to report to the agency about adverse events, product problems, and medication/device use errors that occur with FDA regulated products, including drugs, biologicals, medical devices, special nutritional products, dietary supplements, and non-prescription (over-the-counter (OTC)) human drug products marketed without an approved application.

DATES: Submit written or electronic comments on the collection of information by April 15, 2008.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

MedWatch: The FDA Medical Products Reporting Program, Form FDA 3500 and Form FDA 3500A—(OMB Control Number 0910–0291)—Extension

Under sections 505, 512, 513, 515, and 903 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355, 360b, 360c, 360e, and 393), and section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to ensure the safety and effectiveness of drugs, biologics, and devices. Under section 502(a) of the act (21 U.S.C. 352(a)), a drug or device is misbranded if its labeling is false or misleading. Under section 502(f)(1) of the act it is misbranded if it fails to bear adequate warnings, and under section 502(j), it is misbranded if it is dangerous to health when used as directed in its labeling.

Under section 4 of the Dietary Supplement Health and Education Act of 1994 (Public Law 103–417), 21 U.S.C. 342 is amended so that FDA must bear the burden of proof to show a dietary supplement is unsafe.