certain individuals described in the statute as: (1) Undocumented aliens; (2) aliens who have been paroled into the United States at a United States port of entry for the purpose of receiving eligible services; and (3) Mexican citizens permitted to enter the United States for not more than 30 days under the authority of a biometric machine readable border crossing identification card (also referred to as a ''laser visa'') issued in accordance with the requirements of regulations prescribed under a specific section of the Immigration and Nationality Act as published in the Bureau of Customs and Border Protection's interim final rule dated August 13, 2004.; *Frequency:* Other—as needed; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and State, Local or Tribal Governments; *Number of Respondents:* 7,503,000; *Total Annual Responses:* 7,512,000; *Total Annual Hours:* 634,000.

2. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Electronic Data Interchange (EDI) Enrollment Form and Centers for Medicare and Medicaid Services EDI Registration Form; *Form No.:* CMS–10164 (OMB # 0938–NEW); *Use:* CMS is requiring that providers who wish to conduct Electronic Data Interchange (EDI) transactions, specifically the HIPAA Eligibility Inquiry and Response (270/271) directly with CMS at the Baltimore data center, provide certain information related to their organization and/or organizations conducting EDI business on their behalf. Health care providers, clearinghouses, and health plans that wish to access the Medicare system for the purposes of conducting other EDI business transactions are also required to complete this form. Furthermore, CMS has incorporated changes to the collection as a result of public comments. One specific comment resulted in the combining of the information collected related to Medicare Modernization Act (MMA) section 1011 and Medicare Fee-For Service Part A and Part B. Both programs collect similar information for the purposes of provider enrollment and trading partner profile information related to the exchange of EDI transactions. To further reduce the burden on providers enrolling in either the MMA section 1011 and/or the Medicare Fee-For Service program the CMS–10164 collection will change terms from ''Carrier/FI'' to ''Medicare contractor''. The purpose is to generically refer to the organization that CMS contracts with to operate the specific program function such as MMA section 1011 or Medicare Part A, Medicare Part B for a specific jurisdiction. The information will be used to assure that profile data for those entities that access the section 1011 and/or Medicare system are entered appropriately. *Frequency:* Recordkeeping and Reporting—Other (As-Needed); *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 1,220,000; *Total Annual Responses:* 1,220,000; *Total Annual Hours:* 400,000.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Retiree Drug Subsidy (RDS) Application and Instructions; *Form Number:* CMS'10156 (OMB#: 0938'' 0957); *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 and implementing regulations at 42 CFR subpart R plan sponsors (employers,unions) who offer prescription drug coverage to their qualified covered retirees are eligible to receive a 28% taxfree subsidy for allowable drug costs. In order to qualify, plan sponsors must submit a complete application to CMS with a list of retirees for whom it intends to collect the subsidy; *Frequency:* Quarterly, Monthly, Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Federal, State, local and/or tribal Government; *Number of Respondents:* 50,000; *Total Annual Responses:* 50,000; *Total Annual Hours:* 2,025,000.

To obtain copies of the supporting statement and any related forms for these paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/regulations/pra/*, 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 December 19, 2005. OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, CMS Desk Officer,New Executive Office Building, Room 10235,Washington, DC 20503.

Dated: November 9, 2005.

Michelle Shortt,

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

[FR Doc. 05–22904 Filed 11–17–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10173, CMS–437A and CMS–437B]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

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:* New Collection; *Title of Information Collection:* Individuals Authorized Access to the CMS Computer Services; *Form Number:* CMS–10173 (OMB#: 0938–NEW); *Use:* The Centers for Medicare and Medicaid Services (CMS) is requesting the Office of Management and Budget (OMB) approval of the Individuals Authorized to Customer Service Application for Access to CMS Computer Systems. CMS has planned to provide a centralized user provisioning and administration service that supports the creation, deletion, and lifecycle management of enterprise identities. This service creates accounts, supports Role Based Access Control (RBAC), the form flow approval process and enterprise identity audit and recertification, and provides business application integration points. An application integration point allows

business application owners to use the form flow process of the user provisioning service to approve or deny requests for access to business applications. The primary purpose of this system is to implement a unified framework for managing user information and access rights, for those individuals who apply for and are granted access across multiple CMS systems and business contexts. Information in this system will also be used to: (1) Support regulatory and policy functions performed within the Agency or by a contractor or consultant; (2) support constituent requests made to a Congressional representative; and (3) to support litigation involving the Agency related to this system. We have provided background information about the proposed system in the ''Supplementary Information'' section below. Although the Privacy Act requires only that the ''routine use'' portion of the system be published for comment, CMS invites comments on all portions of this notice. See ''Effective Dates'' section for comment period; *Frequency:* Other—As required; *Affected Public:* Business or other-for-profit, Individuals or Households, Not-for-profit institutions, Federal government, and State, Local, or Tribal Government; *Number of Respondents:* 60,000,000; *Total Annual Responses:* 60,000,000; *Total Annual Hours:* 15,000,000.

2. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Rehabilitation Unit Criteria Work Sheet and Rehabilitation Hospital Criteria Work Sheet and Supporting Regulations at 42 CFR 488.26; *Form Number:* CMS–437A and CMS–437B (OMB#: 0938–NEW—NOTE: These instruments are currently approved under 0938–0358 but are being carved out into a separate collection as they are updated more frequently.); *Use:* The rehabilitation hospital and rehabilitation unit criteria work sheets are necessary to verify that these facilities/units comply and remain in compliance with the exclusion criteria for the Medicare prospective payment system; *Frequency:* Annually; *Affected Public:* Business or other-for-profit, Not-for-profit institutions, and State, Local, or Tribal Government; *Number of Respondents:* 1227; *Total Annual Responses:* 1227; *Total Annual Hours:* 306.75.

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/regulations/pra/,* 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 at the address below, no later than 5 p.m. on January 17, 2006. CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: William N. Parham, III, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: November 9, 2005.

Michelle Shortt,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005P–0305]

Request for Comment on the Status of Pyridoxamine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of opportunity to comment.

SUMMARY: The Food and Drug Administration (FDA) is announcing that comments related to the status of pyridoxamine may be submitted until December 19, 2005. FDA is requesting comments in response to the submission of a citizen petition requesting, among other things, that the agency determine the status of pyridoxamine. All comments postmarked on or before December 19, 2005 will be accepted as part of the official record for this matter.

DATES: Submit written comments by December 19, 2005.

ADDRESSES: Submit written comments on the status of pyridoxamine 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.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Robert Moore, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1441.

SUPPLEMENTARY INFORMATION: On July 29, 2005, FDA received a citizen petition submitted, under 21 CFR 10.30, by the law firm Morgan Lewis & Bockius, LLP, on behalf of BioStratum, Inc. The petition requests that the agency: (1) State in writing that dietary supplements that contain pyridoxamine are adulterated under the Federal Food, Drug, and Cosmetic Act; (2) exercise its enforcement authority under the act to remove from interstate commerce dietary supplements containing pyridoxamine; and (3) not place this citizen petition in the agency's docket for premarket notifications for new dietary ingredients (Docket No. 2004N–0454).

In its citizen petition, BioStratum, Inc., states, among other things, that it is the manufacturer of Pyridorin (pyridoxamine dihydrochloride), which is the subject of an investigational new drug application (IND) that was filed with FDA in July 1999 for use as a potential therapeutic agent to slow or prevent the progression of diabetic nephropathy in patients with type 1 and type 2 diabetes. The petition further states that substantial clinical trials have been conducted for this drug and that the existence of those studies has been made public. In addition, the petition states that pyridoxamine was not marketed as a dietary supplement or as a food prior to Pyridorin's authorization for investigation as a new drug under an IND.

FDA has considered the information and legal argument set forth in the petition. Based on the facts set forth in the petition, the agency tentatively concludes that pyridoxamine, the active moiety[1] of pyridoxamine dihydrochloride, is excluded from the dietary supplement definition under the exclusion clause in 21 U.S.C. 321(ff)(3)(B)(ii) and therefore may not be marketed as or in a dietary supplement. However, although the petition asserts that there is no evidence that pyridoxamine was marketed as a dietary ingredient or as a food prior to the authorization of Pyridorin for investigation under an IND, the agency is interested in receiving information, if any, that bears on pyridoxamine's prior marketing as a dietary ingredient or as a food, as well as other information that would inform the agency's final decision on the status of pyridoxamine.

[1] Under 21 CFR 316.3(b)(2), ''active moiety'' means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.