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.

[FR Doc. 05–22906 Filed 11–17–05; 8:45 am]

BILLING CODE 4120–01–P

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.

In order to afford all interested parties adequate opportunity to participate in this matter, the agency requests comments and supporting information related to this matter. 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 10, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–22884 Filed 11–17–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–05–8004]

Implementation Plan on the Sharing of Confidential Information Between the European Commission's Health and Consumer Protection Directorate General and the United States Food and Drug Administration of the Department of Health and Human Services

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of an Implementation Plan on the sharing of confidential information between the European Commission's Health and Consumer Protection Directorate General and the United States Food and Drug Administration of the Department of Health and Human Services. The purpose is for both participants to cooperate to facilitate the sharing of documents and/or information related to food safety.

DATES: The agreement became effective on September 23, 2005.

FOR FURTHER INFORMATION CONTACT: Matthew E. Eckel, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville MD, 20857, 301–827–4480; FAX 301–480–0716.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and Implementation Plans between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this Implementation Plan.

Dated: November 10, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S