

and Not-for-profit institutions; *Number of Respondents*: 2,458,549; *Total Annual Responses*: 981,642; *Total Annual Hours*: 547,578.

2. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Information Collection Requirements in 42 CFR 478.18, 478.34, 478.36, 478.42, QIO Reconsiderations and Appeals; *Use*: In the event that a beneficiary, provider, physician, or other practitioner does not agree with the initial determination of a Quality Improvement Organization (QIO) or a QIO subcontractor, it is within that party's rights to request reconsideration. The information collection requirements 42 CFR 478.18, 478.34, 478.36, and 478.42, contain procedures for QIOs to use in reconsideration of initial determinations. The information requirements contained in these regulations are on QIOs to provide information to parties requesting the reconsideration. These parties will use the information as guidelines for appeal rights in instances where issues are actively being disputed.; *Form Number*: CMS-R-72 (OMB#: 0938-0443); *Frequency*: Reporting—On occasion; *Affected Public*: Individuals or Households and Business or other for-profit institutions; *Number of Respondents*: 2,590; *Total Annual Responses*: 5,228; *Total Annual Hours*: 2,822.

3. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Certification Statement for Electronic File Interchange Organizations (EFIOS) that Submit National Provider Identifier (NPI) Data to the National Plan and Enumeration System; *Use*: The EFI process is designed to allow organizations to submit NPI application information for large numbers of providers in a single file. Once it has obtained and formatted the necessary provider data, the EFIO will electronically submit the file to NPPES for processing. As each file can contain up to approximately 100,000 records, or provider applications, the EFI process greatly reduces the paperwork and overall administrative burden associated with enumerating providers; *Form Number*: CMS-10175 (OMB#: 0938-0984); *Frequency*: Reporting—Other, One-time; *Affected Public*: Business or other for-profit, and Not-for-profit institutions; *Number of Respondents*: 1000; *Total Annual Responses*: 1000; *Total Annual Hours*: 3000.

4. *Type of Information Collection Request*: Extension of a currently

approved collection; *Title of Information Collection*: Survey of Newly Eligible Medicare Beneficiaries; *Use*: CMS is responsible for providing beneficiaries with the Medicare program information they need to effectively choose the health care plan best suited to their needs. In order to provide such information, CMS needs to know (1) Whether or not new enrollees are aware of the choices they have, (2) what beneficiaries understand about the basic elements of the Medicare program, (3) what other sources currently provide Medicare-related information, and (4) how all of these items vary across beneficiary subpopulations. To this end, CMS must have the ability to measure over time what beneficiaries know and understand about the Medicare program. Measuring beneficiaries' information needs and knowledge over time will help CMS evaluate its impact on information/education, population changes and other initiatives; *Form Number*: CMS-10050 (OMB#: 0938-0869); *Frequency*: Reporting—Quarterly; *Affected Public*: Individuals or Households; *Number of Respondents*: 2400; *Total Annual Responses*: 2400; *Total Annual Hours*: 800.

5. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: SSO Report of State Buy-in Problem and Supporting Regulations in 42 CFR 407.40; *Use*: Under the State Buy-In program, States enroll certain groups of needy people under the Part B Supplementary Medical Insurance (SMI) Program and pay their premiums. The purpose of the "buy-in" is to allow the States to provide SMI protection to certain groups of needy individuals as part of its total assistance plan. Generally, States "buy-in" for individuals who are categorically needy under Medicaid and meet the eligibility requirements for Medicare Part B. States can also include in their buy-in agreement those eligible for medical assistance only. The CMS-1957 is used in the resolution of beneficiary complaints regarding State buy-in. This form facilitates the coordination of efforts between the SSO, State Medicaid Agencies, and CMS in the resolution of a beneficiary's State buy-in problem; *Form Number*: CMS-1957 (OMB#: 0938-0035); *Frequency*: Reporting—On occasion; *Affected Public*: Federal government, Individuals or Households, and State, Local, and Tribal governments; *Number of Respondents*: 6,600; *Total Annual Responses*: 6,600; *Total Annual Hours*: 2,366.

6. *Type of Information Collection Request*: Extension of a currently

approved collection; *Title of Information Collection*: Home Health Agency Survey and Deficiencies Report, Home Health Functional Assessment Instrument and Supporting Regulations in 42 CFR 488.26 and 442.30; *Use*: In order to participate in the Medicare program as a Home Health Agency (HHA) provider, the HHA must meet Federal Standards. These forms used to record information about patients' health and provider compliance with requirement and report information to the Federal Government; *Form Number*: CMS-1515 & 1572 (OMB#: 0938-0355); *Frequency*: Reporting—Annually; *Affected Public*: Business or other for-profit, Individuals or Households, and Not-for-profit institutions; *Number of Respondents*: 24,150; *Total Annual Responses*: 24,150; *Total Annual Hours*: 3,864.

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](mailto: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 June 13, 2006.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—B, Attention: William N. Parham, III, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: April 4, 2006.

**Michelle Shortt,**

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

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0107]

### Food and Drug Administration-Regulated Products Containing Nanotechnology Materials; Planning of Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is planning a public meeting on FDA-regulated products containing nanotechnology materials. The purpose of the meeting will be to help FDA further its understanding of developments in nanotechnology materials that pertain to FDA-regulated products. FDA is interested in learning about the kinds of new nanotechnology material products under development in the areas of foods (including dietary supplements), food and color additives, animal feeds, cosmetics, drugs and biologics, and medical devices; whether there are scientific issues that should be addressed; and any other issues about which the regulated industry, academia and the interested public may wish to inform FDA concerning the use of nanotechnology materials in FDA-regulated products.

**DATES AND TIMES:** The public meeting will be held in mid-October 2006. Details on the date and time of the meeting will be provided in a subsequent **Federal Register** notice.

**ADDRESSES:** The public workshop will be held in the Washington, DC metropolitan area. The meeting address will be provided in a subsequent **Federal Register** notice and posted at <http://www.fda.gov/nanotechnology>.

Submit written comments 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>. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

*For information about this document:*  
Poppy Kendall, Food and Drug Administration (HF-11), 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360, FAX: 301-594-6777, e-mail: [Poppy.Kendall@FDA.HHS.Gov](mailto:Poppy.Kendall@FDA.HHS.Gov).

**SUPPLEMENTARY INFORMATION:**

**I. Why Are We Holding a Public Meeting?**

Nanotechnology is defined in a variety of ways. The National Nanotechnology Initiative (a U.S. Government research and development coordinating program) refers to nanotechnology as "the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications" (<http://www.nano.gov>). A nanometer is a billionth of a meter, and is approximately the width of 10

hydrogen atoms lined up side by side. (A human hair is about 80,000 nanometers in width. Deoxyribonucleic acid (DNA) is about 2.5 nanometers in width.)

Due to their small size and extremely high ratio of surface area to volume, nanotechnology materials often have chemical or physical properties that are different from those of their larger counterparts. Such differences include altered magnetic properties, altered electrical or optical activity, increased structural integrity, and increased chemical and biological activity. Because of these properties, nanotechnology materials have great potential for use in a vast array of products. Also because of some of their special properties, they may pose different safety issues than their larger counterparts. Of particular interest to FDA, nanotechnology materials may enable new developments in implants and prosthetics, drug delivery, and food processing, and may already be in use in some cosmetics and sunscreens. As part of its critical path initiative, FDA is interested in learning if there are opportunities for it to help overcome scientific hurdles that may be inhibiting the use of nanotechnology in medical product development.

We will be holding this meeting because we are interested in learning about the kinds of new nanotechnology material products under development in the areas of foods (including dietary supplements), food and color additives, animal feeds, cosmetics, drugs and biologics, and medical devices; whether there are scientific issues that should be addressed; and any other issues about which the regulated industry, academia and the interested public may wish to inform FDA concerning the use of nanotechnology materials in FDA-regulated products.

For more information about FDA's role regarding nanotechnology products, see our Web page at <http://www.fda.gov/nanotechnology>. We are announcing our plans now to hold a meeting to give ourselves and participants ample time to prepare.

**II. How Can You Participate?**

Details on registration and the meeting agenda will be provided in a subsequent **Federal Register** notice and at <http://www.fda.gov/nanotechnology>. To help us plan the logistics and agenda for the meeting, we would appreciate receiving expressions of interest from those planning on attending or presenting at the meeting, via e-mail or phone to Poppy Kendall (see **FOR FURTHER INFORMATION CONTACT**). We will attempt to obtain a venue and structure

the meeting to accommodate the level of expressed interest and to address a range of topics, but will not begin the registration process until after publication of the subsequent **Federal Register** notice.

**III. How Should You Send Comments on the Issues?**

Interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). 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.

Dated: March 21, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2003D-0206]

**Guidance for Industry on Exocrine Pancreatic Insufficiency Drug Products—Submitting New Drug Applications; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Exocrine Pancreatic Insufficiency Drug Products—Submitting NDAs." This guidance is intended to assist manufacturers of exocrine pancreatic insufficiency drug products in preparing and submitting documentation to meet new drug application (NDA) requirements for the drug products.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that