docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *Juanmanuel.vilela@fda.hhs.gov.*

**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.

**Appeals of Science-Based Decisions Above the Division Level at CVM—21 CFR Part 10.75 (OMB Control Number 0910–0566—Extension)**

*Respondents:* Respondents to this collection of information are applicants that wish to submit a request for review of a scientific dispute.

CVM's Guidance for Industry #79—''Dispute Resolution Procedures for Science-based Decisions on Products Regulated by the Center for Veterinary Medicine'' describes the process by which CVM formally resolves disputes relating to scientific controversies. A scientific controversy involves issues concerning a specific product regulated by CVM related to matters of technical expertise and requires specialized education, training, or experience to be understood and resolved. Further, the guidance details information on how the Agency intends to interpret and apply provisions of the existing regulations regarding internal Agency review of decisions. In addition, the guidance outlines the established procedures for persons who are sponsors, applicants, or manufacturers, for animal drugs or other products regulated by CVM, who wish to submit a request for review of a scientific dispute. When a sponsor, applicant, or manufacturer has a scientific disagreement with a written decision by CVM, they may submit a request for a review of that decision by following the established Agency channels of supervision for review.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| 10.75 | 1 | 3 | 3 | 10 | 30 |

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

This estimated annual reporting burden is based on CVM's experience over the past 3 years in handling formal appeals for scientific disputes. The number of respondents multiplied by the number of responses per respondent equals the total annual responses. The average burden per response (in hours) is based on discussions with industry and may vary depending on the complexity of the issue(s) involved and the duration of the appeal process.

Dated: July 7, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–17532 Filed 7–12–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0567]**

## Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Restaurant Menu and Vending Machine Labeling: Recordkeeping and Mandatory Third Party Disclosure Under Section 4205 of the Patient Protection and Affordable Care Act of 2010

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Restaurant Menu and Vending Machine Labeling: Recordkeeping and Mandatory Third Party Disclosure Under Section 4205 of the Patient Protection and Affordable Care Act of 2010'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 31, 2011 (76 FR 5380), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0665. The

approval expires on June 13, 2014. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: July 7, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–17571 Filed 7–12–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0012]**

### Critical Path Manufacturing Sector Research Initiative (U01)

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of a cooperative agreement with the National Institute for Pharmaceutical Technology and Education Initiative (NIPTE).

Development of the Critical Path Manufacturing Sector Initiative has focused attention on the continuing need for this kind of research in a way that can improve reliability of pharmaceutical product manufacturing and quality across the entire industry. This shared knowledge will increase the likelihood of successfully manufacturing products that have been identified in the clinical development community. The goal of this agreement is to improve the overall manufacturing and quality and the knowledge base.

**DATES:** Important dates are as follows:

1. The application due date is July 20, 2011.

2. The anticipated start date is August 31, 2011.

3. The opening date is July 13, 2011.

4. The expiration date is July 22, 2011.

*For Further Information and Additional Requirements Contact:*

*For Programmatic and Scientific Questions and Concerns contact:*

Jon Clark, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4178, Silver Spring, MD 20993, 301–796–2400; E-mail: *Jon.Clark@fda.hhs.gov.*

*For Administrative and Financial Questions and Concerns contact:* Gladys Melendez, Office of Acquisitions and Grant Support, Food and Drug Administration, 5630 Fishers Lane, rm. 1078, Rockville, MD 20857, 301–827–7175; E-mail: *gmb@fda.hhs.gov.*

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm088761.htm* under the ''Regulatory Information'' section. The title of the page is ''Research Acquisitions.''

**SUPPLEMENTARY INFORMATION:**

#### I. Funding Opportunity Description

*Funding Opportunity Number:* RFA–FD–11–014.

*Catalog of Federal Domestic Assistance:* 93.103.

*A. Background*

The Office of Pharmaceutical Science has conducted research within the academic community through contracts in order to improve the overall manufacturing and quality knowledge base. This research is important to the public sector, because research conducted in pharmaceutical sciences related to product quality is typically kept proprietary.

Development of the Critical Path Manufacturing Sector Initiative has focused attention on the continuing need for this kind of research in a way that can improve reliability of pharmaceutical product manufacturing and quality across the entire industry. This shared knowledge will increase the likelihood of successful manufacturing.

*B. Research Objectives*

The grant will support programs and research as described in the following paragraphs, related to the manufacturing of drugs, biological products, and medical devices:

- Education and training in the field of manufacturing and scale-up, for product development partnerships, academic scientists, other product developers and product application reviewers.
- Development of platform strategies and standardized approaches for medical product manufacturing to shorten timelines for manufacturers to produce quality medical products at commercial scale. This will provide publicly available models for manufacturing and scale-up that will help enable small firms to expeditiously market important treatments.
- Development of analytical methodologies and advanced computational methodologies to better characterize complex molecules and complex mixtures of molecules is needed to better understand and control manufacturing processes and product quality. Specific analytical techniques will better enable standardized approaches to manufacturing control and advance computational technologies will help to identify atypical samples of complex molecules. These advances will help assure pharmaceutical quality for the American public.
- Research into improved techniques for collection and analysis of process data to control processes and to ensure that they are in statistical control will be done. This includes science-based flexible and adaptive approaches to manufacturing utilizing feed forward and feed backward information flow. Standardized approaches to assuring product quality using manufacturing and analytical data will support continued product quality and lessen manufacturing failures thus decreasing shortages of medically necessary products.
- Development of techniques for assuring product quality using surrogates for desired clinical results will improve understanding of quality target product profile. This approach takes advantage of the potential to use existing clinical data to determine clinically relevant specifications including unit-to-unit variability, drug dissolution, and other material or product attributes, and to support future manufacturing improvements while maintaining product quality.
- Creating simulation models for manufacturing techniques including but not limited to biotech fermentation and cell culture, small molecule crystallization, freeze drying techniques, and precision tablet coating will enhance industry knowledge. These models will enable a more predictable approach to manufacturing development and design of control systems. This predictability will shorten the critical path pipeline from laboratory to clinic and support continual improvement to achieve product quality of the drug's lifecycle.
- Creating simulation models for complex drug delivery devices such as dry product inhalers, transdermal patches, and liposomal products to better understand the product design and performance and to control the critical manufacturing parameters. These models will aid to speed the development of novel dosage forms and decrease the failure rates of these products.
- Research into product formulation for special patient populations or product formulation to ensure chemical stability of active ingredients will shorten formulation development and