TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN[1]

| 21 CFR Section | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure (in hours) | Total hours |
|---|---|---|---|---|---|
| 107.230 | 2 | 1 | 2 | 50 | 100 |
| 107.260 | 1 | 1 | 1 | 25 | 25 |
| Total | | | | | 125 |

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

New table 2 reports the Agency's third-party disclosure burden estimates for §§ 107.230 and 107.260. The estimated burden hours per disclosure is an average based on the Agency's experience. The third-party disclosure burden in § 107.230 is the requirement to promptly notify each affected direct-account (customer) about the recall and if the recalled formula presents a risk to human health, the requirement that the recalling firm must also request that each establishment that sells the recalled formula post (at the point of purchase) a notice of the recall. We estimate that two respondents will conduct infant formula recalls under § 107.230 and that it will take a respondent 50 hours to comply with the third-party disclosure requirements of that section, for a total of 100 hours. The third-party disclosure burden in § 107.260 is the requirement to issue additional notifications where the recall strategy or implementation is determined to be deficient. We estimate that one respondent will issue additional notifications under § 107.260 and that it will take a respondent 25 hours to comply with the third-party disclosure requirements of that section, for a total of 25 hours.

Dated: August 12, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–21040 Filed 8–17–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0402]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Petitions for Exemption From Preemption

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by September 19, 2011.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *Fax:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0277. Also include the FDA docket number found in brackets in the heading of this document.

**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 compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### State Petitions for Exemption From Preemption—21 CFR 100.1(d) (OMB Control Number 0910–0277)—Extension

Under section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343–1(b)), States may petition FDA for exemption from Federal preemption of State food labeling and standard of identity requirements. Section 100.1(d) (21 CFR 100.1(d)) sets forth the information a State is required to submit in such a petition. The information required under § 100.1(d) enables FDA to determine whether the State food labeling or standard of identity requirement satisfies the criteria of section 403A(b) of the FD&C Act for granting exemption from Federal preemption.

In the **Federal Register** of June 10, 2011 (76 FR 34082), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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 |
|---|---|---|---|---|---|
| 100.1(d) | 1 | 1 | 1 | 40 | 40 |

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

The reporting burden for § 100.1(d) is minimal because petitions for exemption from preemption are seldom submitted by States. In the last 3 years, FDA has not received any new petitions for exemption from preemption; therefore, the Agency estimates that one or fewer petitions will be submitted annually. Although FDA has not received any new petitions for exemption from preemption in the last 3 years, it believes these information collection provisions should be extended to provide for the potential future need of a State or local

government to petition for an exemption from preemption under the provisions of section 403A of the FD&C Act.

Dated: August 12, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–21041 Filed 8–17–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0012]**

### Direct Discovery of HLA Associated Influenza Epitopes Isolated From Human Cells for Vaccine and Therapeutic Evaluation and Development (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 sole source cooperative agreement with the University of Oklahoma Health Sciences Center. The goal of the FDA, Center for Drug Evaluation and Research, Office of Chief Scientist, is to develop technology to molecularly characterize peptide epitopes that are processed and presented on soluble HLA (human leucocyte antigen) expressed by human cells. Initial studies will examine and characterize influenza peptides isolated from several different soluble Class I HLAs produced from influenza infected human lung cell lines. There is a growing interest in developing universal vaccines for influenza by targeting conserved internal proteins to stimulate cross-protective CTLs (cytolytic T lymphocyte) to provide long-lasting immunity. It is therefore critically important to identify which viral epitopes are generated by antigen processing in influenza infected lung cells, the target cells of cell mediated immune response to respiratory viruses. FDA seeks a collaboration to develop this technology for this purpose which can then be applied to identifying and characterizing other HLA-presented epitopes in viral infections, cancer, and immune toxicities.

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

1. The application due date is September 1, 2011.

2. The anticipated start date is November 1, 2011.

3. The opening date is August 18, 2011.

4. The expiration date is November 2, 2011.

**FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:**

*For Programmatic questions and concerns contact:* Michael Norcross, Center for Drug Evaluation and Research, Food and Drug Administration, 9000 Rockville Pike, N29B, Rm. 4NN (HFD 122), Bethesda, MD 20892, *Telephone:* 301–827–0793; *E-mail: Michael.norcross@fda.hhs.gov.*

*For Financial and Administrative questions and concerns contact:* Gladys M. Bohler, Food and Drug Administration, Office of Acquisitions and Grant Services, 5630 Fisher's Lane, Rm. 1078 (HFA 500), Rockville, MD 20857, *Telephone:* 301–827–7175, *E-mail: gladys.bohler@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.*

**SUPPLEMENTARY INFORMATION:**

## I. Funding Opportunity Description

*Funding Opportunity Number:* RFA–FD–12–001.

*Catalog of Federal Domestic Assistance Number:* 93.103.

### *A. Background*

Knowledge on how viral and self proteins are processed and presented in HLA molecules is important to understand how the body defends itself from infection and how immune responses can lead to tissue toxicities. Developing technology to allow direct identification of epitopes bound by HLA molecules is critical to vaccine and therapeutic immune strategies. FDA is interested in collaborative research to develop and implement this technology which will be valuable in evaluation and review of vaccines and therapeutics. Initial studies will address identifying epitopes from influenza that are presented by different HLA alleles in infected lung cells.

Influenza virus infection affects a significant proportion of the population and is associated with serious morbidity and mortality. Although many epitopes can be predicted by computer programs and by screening peripheral blood cells with panels of viral peptides from influenza, the peptides that are presented on the infected target cells in the tissues and the infiltrating T cells that recognize the HLA-peptide complexes are the critical elements to control and recover from infection. The technology of directly identifying viral epitopes in HLA can elucidate viral targets for T cells and provide the foundation for new approaches for rapid development of effective vaccines. More effective vaccines to prevent and control influenza infections will have broad public health benefits by reducing morbidity and mortality of this infectious disease.

### *B. Research Objectives*

For this purpose, a direct epitope elution approach is needed to allow milligram quantities of HLA-peptide complexes to be purified from influenza infected lung cells lines that express soluble HLA. Human lung cell lines engineered to secrete soluble HLA from three supertypes (A*01, A*03, and B*27) should be infected with at least two current influenza strains and HLA collected during infection. HLA will be purified and bound peptides eluted. Influenza peptides should be systematically identified by mass spectrometry analysis and sequencing. Synthetic viral peptides can then be tested for binding to recombinant HLA to verify binding specificity and affinity. Influenza epitopes identified in this initial phase of the project can be evaluated for immunogenicity and antigenicity in follow up studies.

This project will provide the regulatory science to facilitate development and evaluation of direct discovery of HLA presented epitopes. The direct epitope methodology will be applied to current influenza strains initially, but has the flexibility to address novel pandemic strains and other pathological agents.

*Goal 1:* Identify virus-encoded class I HLA peptides presented during influenza infection of human lung cells.

*Goal 2:* In vitro validation of class I HLA-presented influenza peptides.

*Goal 3:* Develop HLA-epitope direct-discovery technology for use in FDA laboratories.

### *C. Eligibility Information*

The technology requires extensive infrastructure for growing cells, purifying HLA from culture supernatants, and for mass spectrometry analysis. Staff at the University of Oklahoma Health Sciences Center are leaders in this technology and have published the first reports on applying this method to influenza. Support of this project will allow the extension of the methodology to examine other HLA types. FDA believes this is a novel and valuable methodology that should be implemented at FDA. Funding this collaborative initiative will allow FDA to acquire the proteomic expertise, training, and tissue culture support to establish a laboratory in the field of immunoproteomics. The direct