DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–New; 30-day notice]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection 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.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office on (202) 690–5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at 202–395–5806.

Proposed Project: Prevention and Wellness-Leveraging National Organizations- OMB No. 0990–New-Office of Public Health and Science.

Abstract: The Office of Public Health and Science is requesting an approval by OMB on a new collection. The American Recovery and Reinvestment Act (ARRA) Prevention and Wellness-Leveraging National Organizations is a cooperative agreement program authorized under 42 U.S.C. 300k–1, 300, section 1701 of the Public Health Service Act, as amended. The funding opportunity focuses on two categories of activities:

- Category A: Obesity prevention through improved nutrition and increased physical activity
- Category B: Tobacco prevention and control

The National Organizations who receive funding will be supporting Communities Putting Prevention to Work (CPPW)-funded communities by providing expertise and technical assistance to help implement select MAPPS (Media, Access, Point of Purchase/Promotion, Pricing, and Social Support and Services) strategies through national organizations' systems and networks. The National Organizations will work to sustain community prevention efforts beyond Recovery Act CPPW funding and support the National Prevention Media Initiative through co-branding and augmenting HHS-developed media campaigns in communities.

The outcome measures that will be collected from funded National Organizations include approval/enactment of MAPPS-related policy, systems, and environmental change in physical activity, nutrition, and tobacco in funded communities. Since a critical component of the National Organizations is to support and assist CPPW-funded communities with their expert resources, the National Organizations and the CPPW-funded communities will share ownership of the same outcome measures. Because the National Organizations and their local affiliates have a distinct supporting role in these community-wide efforts, the output measures track the kinds of added-value to be derived from involvement of the National Organizations and its local affiliates in the community-wide efforts which should help drive the outcome measure.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden (in hours) per response	Total burden hours
National Organizations Measures Instrument.	Cooperative Agreement recipients—National Organizations.	10	4	2	80

Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2010–30435 Filed 12–3–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0595]

Agency Information Collection Activities; Proposed Collection; Comment Request; Exports: Notification and Recordkeeping Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the notification and recordkeeping requirements for persons exporting human drugs, biological products, devices, animal drugs, food, and cosmetics that may not be marketed or sold in the United States.

DATES: Submit either electronic or written comments on the collection of information by February 4, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug

Administration, 1350 Piccard Dr., PI50–410B, Rockville, MD 20850, 301–796–3794, *E-mail*: *Jonnalynn.Capezzuto@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.

Exports: Notification and Recordkeeping Requirements—21 CFR Part 1 (OMB Control Number 0910–0482)—Extension

The respondents to this information collection are exporters who have notified FDA of their intent to export unapproved products that may not be sold or marketed in the United States as allowed under section 801(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381). In general, the notification identifies the product being exported (*e.g.,* name, description, and in some cases, country of destination) and specifies where the notification should be sent. These notifications are sent only for an initial export; subsequent exports of the same product to the same destination (or, in the case of certain countries identified in section 802(b) of the FD&C Act (21 U.S.C. 382)) would not result in a notification to FDA.

The recordkeepers for this information collection export human drugs, biologics, devices, animal drugs, foods, and cosmetics that may not be sold in the United States and maintain records demonstrating their compliance with the requirements in section 801(e)(1) of the FD&C Act.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
1.101 (d) to (e)	400	3	1,200	15	18,000

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
1.101 (b) to (c)	320	3	960	22	21,120

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

Dated: November 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30433 Filed 12–3–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2010–E–0032 and FDA–2010–E–0036]

Determination of Regulatory Review Period for Purposes of Patent Extension; STELARA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for *STELARA* and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis