TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Total	.....	.....	.....	.....	29,000

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

TABLE 3—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	Total hours
§§ 107.10(a) and 107.20	5	13	65	8	520

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

In compiling these estimates, we consulted our records of the number of infant formula submissions received in the past. All infant formula submissions may be provided to us in electronic format. The hours per response reporting estimates are based on our experience with similar programs and information received from industry.

We estimate that we will receive 13 reports from 5 manufacturers annually under section 412(d) of the FD&C Act, for a total annual response of 65 reports. Each report is estimated to take 10 hours per response for a total of 650 hours. We also estimate that we will receive one notification under § 106.120(b). The notification is expected to take 4 hours per response, for a total of 4 hours.

For exempt infant formula, we estimate that we will receive two reports from three manufacturers annually under §§ 107.50(b)(3) and (b)(4), for a total annual response of six reports. Each report is estimated to take 4 hours per response for a total of 24 hours. We also estimate that we will receive one notification annually under § 107.50(e)(2) and that the notification will take 4 hours to prepare.

We estimate that 5 firms will expend approximately 20,000 hours per year to fully satisfy the recordkeeping requirements in § 106.100 and that 3 firms will expend approximately 9,000 hours per year to fully satisfy the recordkeeping requirements in § 107.50(c)(3).

We estimate compliance with our labeling requirements in §§ 107.10(a) and 107.20 requires 520 hours annually by 5 manufacturers.

Dated: May 9, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–11631 Filed 5–15–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0873]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Bar Code Label Requirement for Human Drug and Biological Products

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 June 17, 2013.

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 emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0537. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@fda.hhs.gov*.

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.

Bar Code Label Requirement for Human Drug and Biological Products—(OMB Control Number 0910–0537)—Extension

In the **Federal Register** of February 26, 2004 (69 FR 9120), we issued regulations that required human drug product and biological product labels to have bar codes. The rule required bar codes on most human prescription drug products and on over-the-counter (OTC) drug products that are dispensed under an order and commonly used in health care facilities. The rule also required machine-readable information on blood and blood components. For human prescription drug products and OTC drug products that are dispensed under an order and commonly used in health care facilities, the bar code must contain the National Drug Code number for the product. For blood and blood components, the rule specifies the minimum contents of the machine-readable information in a format approved by the Center for Biologics Evaluation and Research Director as blood centers have generally agreed upon the information to be encoded on the label. The rule is intended to help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time.

Most of the information collection burden resulting from the final rule, as calculated in table 1 of the final rule (69 FR 9120 at 9149), was a one-time burden that does not occur after the rule's compliance date of April 26, 2006. In addition, some of the information collection burden estimated

in the final rule is now covered in other OMB-approved information collection packages for FDA. However, parties may continue to seek an exemption from the bar code requirement under certain, limited circumstances. Section 201.25(d) (21 CFR 201.25(d)) requires submission of a written request for an exemption and describes the contents of such requests. Based on the number of exemption requests we have received, we estimate that approximately 2 exemption requests may be submitted annually, and that each exemption request will require 24 hours to complete. This would result in an annual reporting burden of 48 hours.

In the **Federal Register** of August 17, 2012 (77 FR 49818), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden for 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
§ 201.25(d)	2	1	2	24	48

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

Dated: May 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–11630 Filed 5–15–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

A Diagnostic Kit for Assessing Exposure or Infection by the Koala Family of Retroviruses

Description of Technology: Inventors at the NIH have discovered a new family of infectious koala retroviruses that are correlated with the development of malignant neoplasias, including lymphomas and leukemias. This invention relates to a diagnostic kit for assessing exposure or infection by a koala retrovirus. The kit consists of specific primers and probes for the detection of three distinct subtypes of infectious koala retrovirus and may be useful in various species, including humans, primates, and koalas. Infectious koala retroviruses have been shown to infect human cells in culture, though the health implications in humans have not yet been fully determined.

Potential Commercial Applications:

- A diagnostic kit for assessing exposure or infection by the koala family of retroviruses
- May be useful in monitoring effectiveness of antiretroviral treatment

Competitive Advantages: Detection of newly discovered subtypes of infectious koala retroviruses.

Development Stage:

- Early-stage
- In vitro data available

Inventors: Maribeth V. Eiden (NIMH), Wenqin Xu (NIMH), William M. Switzer (CDC), HaoQiang Zheng (CDC)

Intellectual Property: HHS Reference No. E–053–2013/0—US Application No. 61/784,763 filed 14 Mar 2013

Licensing Contact: Charlene Sydnor, Ph.D.; 301–435–4689; *sydnorc@mail.nih.gov*

Collaborative Research Opportunity: The National Institute of Mental Health is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize A Diagnostic Kit for Assessing Exposure or Infection by the Koala Family of Retroviruses. For collaboration opportunities, please contact Suzanne L. Winfield, Ph.D. at *winfiels@mail.nih.gov* or 301–402–4324.

Retroviral Vector Packaging Cell Lines and Purification Methods for Gene Therapy

Description of Technology: This invention relates to a novel gammaretroviral vector packaging cell line and method of producing gammaretroviral vectors suitable for gene therapy. The described vectors may contain the gibbon ape leukemia virus (GALV) envelope with a CD11D8 epitope tag enabling their purification on a monoclonal antibody conjugated column. These vectors have several advantages over existing systems, including a broader host range, higher infectivity, and lower potential for replication. Further, purification of retroviral vector particles via an epitope tag may remove cellular components and debris toxic to target cells and tissues, providing a safer method of delivery for patients receiving gene therapy.

Potential Commercial Applications: Retroviral vector particles for gene therapy.

Competitive Advantages:

- Broader host range
- Higher infectivity
- Lower potential for replication
- Decreased toxicity after purification

Development Stage:

- Early-stage
- In vitro data available

Inventors: Maribeth V. Eiden and Wenqin Xu (NIMH)

Intellectual Property: HHS Reference No. E–036–2013/0—US Application No. 61/759,516 filed 01 Feb 2013

Licensing Contact: Charlene Sydnor, Ph.D.; 301–435–4689; *sydnorc@mail.nih.gov*

Collaborative Research Opportunity: The National Institute of Mental Health is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize