recordkeeping requirements of § 801.150(a)(2) consist of making copies and maintaining the actual reporting requests which were required under the reporting section of this collection. To fulfill this requirement, FDA estimates it will take about 30 minutes to copy each package, for a total of 900 recordkeeping hours and includes $55,800 operating and maintenance costs.

In the **Federal Register** of February 18, 2010 (75 FR 7276), 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	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801.150(e)	90	20	1,800	4	7,200

[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	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
801.150(a)(2)	90	20	1,800	0.5	900

[1] There are no capital costs associated with this collection of information.

Due to a clerical error, the operating and maintenance costs that appeared in a document published in the **Federal Register** of February 18, 2010, were incorrect. There are actually no operating and maintenance costs associated.

Dated: April 21, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–9555 Filed 4–23–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0194]

Draft Guidance for Industry and Food and Drug Administration Staff; Total Product Life Cycle: Infusion Pump—Premarket Notification [510(k)] Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled "Total Product Life Cycle: Infusion Pump—Premarket Notification [510(k)] Submissions." The recommendations in this guidance are intended to improve the safety and effectiveness of these devices. This draft guidance is not final nor is it in effect at this time. Elsewhere in this issue of the **Federal Register**, FDA is announcing a public meeting regarding external infusion pumps.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by July 26, 2010. Submit written or electronic comments on the collection of information by June 25, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Total Product Life Cycle: Infusion Pump—Premarket Notification [510(k)] Submissions" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance 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.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Alan Stevens, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2561, Silver Spring, MD 20993–0002, 301–796–6294.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has seen an increase in the number and severity of infusion pump recalls. Analyses of medical device reports (MDRs) revealed device problems that appear to be a result of faulty design. Between January 1, 2005, and December 31, 2009, FDA received over 56,000 MDRs associated with the use of infusion pumps. Of these reports, approximately 1 percent were reported as deaths, 32 percent were reported as serious injuries, and 64 percent were reported as malfunctions.

The most frequently reported infusion pump device problems are: Software error messages, human factors (which include but are not limited to use error), broken components, battery failure, alarm failure, over infusion, and under infusion. In some reports, the manufacturer was unable to determine or identify the problem and reported the problem as "unknown." Subsequent root cause analyses revealed that many of these design problems were foreseeable and, therefore, preventable.

After evaluating a broad spectrum of infusion pumps across manufacturers, FDA has concluded there are numerous, systemic problems with device design, manufacturing, and adverse event reporting. The agency believes that the draft guidance provides recommendations that will help mitigate current risks and reduce future risks associated with infusion pumps.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will

represent the agency's current thinking on infusion pumps. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive "Total Product Life Cycle: Infusion Pump—Premarket Notification [510(k)] Submissions," you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1694 to identify the guidance you are requesting. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*.

IV. Paperwork Reduction Act of 1995 (the PRA)

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 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.

Draft Guidance for Industry and FDA Staff; Total Product Life Cycle: Infusion Pump—Premarket Notification [510(k)] Submissions

This draft guidance is intended to assist industry in preparing premarket notification submissions for infusion pumps and to identify device features that manufactures should address throughout the total product life cycle. The premarket notification procedures discussed in the draft guidance (21 CFR 807, subpart E) have been approved under OMB control number 0910–0120. The proposed information collection seeks to add clinical or scientific data demonstrating that new or changed infusion pumps are as safe and effective as those legally marketed and do not raise different questions of safety and effectiveness than predicate devices in this generic device type. In this way manufacturers of infusion pumps may demonstrate substantial equivalence and receive premarket clearance for their devices.

Description of Respondents: The respondents to this collection of information are infusion pump manufacturers subject to FDA's laws and regulations. The agency estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Guidance Title: Infusion Pumps—Premarket Notification 510(k) Submissions	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Guidance Section 6—Assurance Case Report	31	1	31	56	1,736

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

FDA estimates it will receive 31 infusion pump submissions annually. The agency reached this estimate by averaging the number of premarket notifications for infusion pumps submitted to FDA over the past 5 years. The draft guidance identifies 56 potential hazards FDA recommends addressing if applicable to a particular device. Although there may be additional hazards identified by a manufacturer, the agency believes these hazards may offset FDA identified hazards not applicable to a particular device. FDA estimates it will take infusion pump manufactures approximately 56 hours (approximately one hour per hazard) to complete the case assurance report described in section 6 of the draft guidance. FDA reached this estimate based on its expectation of the amount of information that will be contained in the report.

Before the proposed information collection provisions contained in this draft guidance become effective, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions. 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.

This draft guidance also refers to previously approved information collections found in FDA regulations. The collections of information in 21 CFR part 803 are approved under OMB control number 0910–0437; the collections of information in 21 CFR part 801 are approved under OMB control number 0910–0485; the collections of information in 21 CFR part 812 are approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814, subparts B and E are approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820 are approved under OMB control number 0910–0073; the collections of information in 21 CFR part 822 are under OMB control number 0910–0449; and the collections of information in 21 CFR 56.115 are approved under OMB control number 0910–0130.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. 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: April 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–9209 Filed 4–23–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, 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.

ADDRESSES: 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.

Peroxidase and Peroxidase Substrate Peptides (PSPs) for Treatment of Inflammatory Disorders and Allergies

Description of Invention: NIH investigators have identified an unexpected and previously unrecognized function of the peroxidase/dual oxidase system in protecting the mucosal surfaces, such as in the gastrointestinal and respiratory tracts. Specifically, NIH investigators have shown that a peroxidase and a dual oxidase (Duox) form a dityrosine network that decreases gut permeability to immune elicitors and prevents activation of epithelial immunity in *An. gambiae* mosquitoes. This technology provides for novel compositions that enhance the formation of a dityrosine network on epithelial cells, such as those found in the gastrointestinal and respiratory tract mucosa of vertebrates, by forming a mucosal barrier on the epithelial surface preventing or inhibiting epithelial cell-mediated inflammatory responses (such as those associated with an inflammatory disease or an allergic reaction). Exemplary compositions include a mammalian or plant heme peroxidase and a peroxidase substrate peptide (PSP).

The compositions of this technology can be useful as therapeutics for several diseases or disorders involving epithelial cell-mediated inflammatory responses (*e.g.,* inflammatory bowel diseases such as Crohn's, and allergic disorders).

Development Status: Early stage.

Applications:

- Therapeutics for autoimmune diseases.
- Therapeutics for food allergies.

Inventors: Carolina Barillas-Mury, Sanjeev Kumar, and Alvara Molina-Cruz (NIAID).

Related Publication: Kumar S, Molina-Cruz A, Gupta L, Rodrigues J, Barillas-Mury C. A peroxidase/dual oxidase system modulates midgut epithelial immunity in *Anopheles gambiae.* Science. 2010 Mar 26;327(5973):1644–1648. [PubMed: 20223948]

Patent Status: U.S. Provisional Application No. 61/308,249 filed 25 Feb 2010 (HHS Reference No. E–073–2010/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Suryanarayana (Sury) Vepa, PhD, J.D.; 301–435–5020; *vepas@mail.nih.gov*.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases, Office of Technology Development, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize *Peroxidase and Peroxidase Substrate Peptides (PSPs) for Treatment of Inflammatory Disorders and Allergies.* Please contact Dana Hsu at 301–496–2644 for more information.

Reversible SNAP–Tag and CLIP–Tag Ligands for Live Cell Imaging

Description of Invention: Recently-developed protein tags enable the specific covalent attachment of synthetic ligands, incorporating fluorophores or other substituted groups, to fusion proteins containing these tags. For example, SNAP and CLIP tags bind O^6-benzylguanine-containing and O2-benzylcytosine containing ligands respectively, which can be derivatized with a wide variety of labels, including fluorescent dyes, affinity probes, and cross-linkers. This system provides a powerful tool to study a variety of highly dynamic processes within cells, including protein trafficking, turnover, and complex formation. However, a substantial limitation to this approach is that labeling is irreversible, due to the formation of a covalent bond between the probe and the protein tag.

The inventors have developed ligands that incorporate a disulfide linkage between the O^6-benzylguanine moiety and the label, allowing selective release of the label from the tagged protein when treated with a reducing agent. The inventors have shown that use of these ligands in conjunction with cell-impermeable reducing agents allows visualization of internalization and trafficking in live cells; these ligands may also be used in other applications in which a cleavable label would be desirable, such as protein purification. This strategy is also applicable to other covalent protein tags, such as the ACP/MCP protein tag system.

Applications:

- Visualization of dynamic processes within cells, including protein trafficking, turnover, and complex formation.
- Live cell imaging.
- Protein purification.

Advantages:

- Allows for selective release of label.
- Accommodates intra- or extra-cellular labeling, and dual labeling.
- Ligands may be derivatized with a wide variety of labels, including fluorescent dyes, affinity probes, and cross-linkers.
- Lower background fluorescence and higher contrast than other systems, such as FlAsH.

Inventors: Nelson B. Cole and Julie G. Donaldson (NHLBI).

Related Publication: In preparation.

Patent Status: U.S. Provisional Application No. 61/312,814 filed 11 Mar 2010 (HHS Reference No. E–057–2010/0–US–01).

Licensing Status: Available for licensing.