Under section 582(h)(4) of the FD&C Act, FDA intends to eventually ''update . . ., as necessary and appropriate, and finalize'' this document to reflect standards for interoperable data exchange at the package level. Because the DSCSA clearly intends for stakeholders to rely upon this guidance document before finalization, however, FDA is immediately implementing this document under 21 CFR 10.115(g)(2). As a result, it reflects FDA's current thinking on this topic and is intended to provide guidance to stakeholders as they implement the DSCSA. Guidance documents generally do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent modifications to those previously approved collections of information found in FDA regulations or guidances.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.regulations.gov.*

Dated: November 21, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28085 Filed 11–26–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1862]

Recommended Warning for Over-the-Counter Acetaminophen-Containing Drug Products and Labeling Statements Regarding Serious Skin Reactions; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Recommended Warning for Over-the-Counter Acetaminophen-Containing Drug Products and Labeling Statements Regarding Serious Skin Reactions.'' The draft guidance is intended to inform manufacturers, members of the medical and scientific community, and other interested persons that at this time we do not intend to object to the marketing of single- and combination-ingredient, acetaminophen-containing, nonprescription (commonly referred to as over-the-counter (OTC)) drug products bearing a warning as described in the draft guidance alerting consumers that the use of acetaminophen may cause severe skin reactions.

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 guidance, submit either electronic or written comments on the draft guidance by January 27, 2015.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit 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: Sudha Shukla, Office of Unapproved Drugs and Labeling Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3110, *Sudha.Shukla@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Recommended Warning for Over-the-Counter Acetaminophen-Containing Drug Products and Labeling Statements Regarding Serious Skin Reactions.'' Acetaminophen, included in many prescription and OTC products, is a common active ingredient indicated to treat pain and reduce fever. On August 1, 2013, FDA issued a Drug Safety Communication (DSC) informing the public that use of acetaminophen has been associated with a risk of rare but serious skin reactions.[1] These skin reactions, including Stevens-Johnson Syndrome, toxic epidermal necrolysis, and acute generalized exanthematous pustulosis, can be fatal.

The DSC explained that reddening of the skin, rash, blisters, and detachment of the upper surface of the skin can occur with the use of drug products that contain acetaminophen. These skin reactions can occur with the first-time use of acetaminophen or at any time while it is being taken. FDA advised health care professionals to be aware of this rare risk and consider acetaminophen, along with other drugs already known to have such an association, when assessing patients with potentially drug-induced skin reactions. FDA also advised that anyone who develops a skin rash or reaction while using acetaminophen or any other pain reliever/fever reducer should stop taking the drug and seek medical attention right away. Furthermore, the announcement advised that anyone who has experienced a serious skin reaction when taking acetaminophen in the past should not take the drug again and should contact their health care professional to discuss alternative pain relievers/fever reducers.

In the announcement, FDA stated that it planned to require manufacturers of acetaminophen-containing prescription

[1] FDA Drug Safety Communication: FDA warns of rare but serious skin reactions with the pain reliever/fever reducer acetaminophen. *http://www.fda.gov/Drugs/DrugSafety/ucm363041.htm.*

drug products to include a warning statement on the product labels to address the risk of serious skin reactions and that it would request the same warning be added by manufacturers of OTC acetaminophen-containing drug products marketed under an approved application. In the fall of 2013, FDA sent letters to manufacturers holding new drug applications (NDA) and abbreviated new drug applications (ANDA) requiring in some cases and requesting in others that the language recommended below be included on the labeling for all products (both prescription and OTC) containing acetaminophen marketed under NDAs and ANDAs. At this time, most of the requested labeling changes have been made by the relevant manufacturers.

FDA also indicated that it planned to encourage manufacturers of acetaminophen-containing drug products marketed under the Tentative Final Monograph for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use, published in the **Federal Register** (53 FR 46204, November 16, 1988) to similarly add a warning about serious skin reactions to the product labels. As noted above, this draft guidance informs manufacturers, members of the medical and scientific community, and other interested persons that at this time we do not intend to object to the marketing of single- and combination-ingredient, acetaminophen-containing, nonprescription (commonly referred to as OTC) drug products bearing a warning as described in the draft guidance alerting consumers that the use of acetaminophen may cause severe skin reactions.

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 the recommended warning for OTC acetaminophen-containing drug products and labeling statements regarding serious skin reactions. 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 statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov.*

III. Paperwork Reduction Act of 1995

Under the draft guidance, manufacturers may add to their drug product labeling a warning statement supplied by FDA that pertains to acetaminophen to address the risk of serious skin reactions. Inclusion of the warning statement on the labels for these drug products would be exempt from review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) because the public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public is not included within the definition of ''collection of information'' (see 5 CFR 1320.3(c)(2)).

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: November 21, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28086 Filed 11–26–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Peer Review Meeting.

Date: December 16, 2014.

Time: 9:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Room 4F100, 5601 Fishers Lane, Rockville, MD (Telephone Conference Call).

Contact Person: Vasundhara Varthakavi, DVM, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 5601 Fishers Lane, Rockville, MD, 301–496–2550, *varthakaviv@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 21, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–28074 Filed 11–26–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, NIH Support for Conferences and Scientific Meetings (Parent R13/U13).

Date: December 15–19, 2014.

Time: 9:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3G62, 5601 Fishers Lane, Rockville, MD 20852, (Virtual Meeting).

Contact Person: Travis J. Taylor, Ph.D., Scientific Review Program DEA/NIAID/NIH/DHHS, 5601 Fishers Lane, Rockville, MD 20892, 240–669–5082, *Travis.Taylor@nih.gov.*