Schedule I synthetic cannabinoids. Synthetic cannabinoids are marketed under the guise of “herbal incense,” and promoted by drug traffickers as legal alternatives to marijuana. On May 11, 2016, XLR11 was permanently controlled as a Schedule I substance under the CSA. As such, additional permanent controls will not be necessary to fulfill U.S. obligations if XLR–11 is controlled under Schedule II of the 1971 Convention on Psychotropic Substances.

FDA, on behalf of the Secretary of HHS, invites interested persons to submit comments on the notifications from the United Nations concerning these drug substances. FDA, in cooperation with the National Institute on Drug Abuse, will consider the comments on behalf of HHS in evaluating the WHO scheduling recommendations. Then, under section 201(d)(2)(B) of the CSA, HHS will recommend to the Secretary of State what position the United States should take when voting on the recommendations for control of substances under the Psychotropic Convention at the CND meeting in March 2017.

Comments regarding the WHO recommendations for control of U–47700 and Butyrylfentanyl under the 1961 Single Convention will also be forwarded to the relevant Agencies for consideration in developing the U.S. position regarding narcotic substances at the CND meeting.

IV. Opportunity for Public Meeting

FDA does not presently plan to hold a public meeting. If any person believes that, in addition to written comments, a public meeting would contribute to the development of the U.S. position on the substances to be considered for control under the Psychotropic Convention, a request for a public meeting and the reasons for such a request should be sent to James R. Hunter (see FOR FURTHER INFORMATION CONTACT) on or before January 23, 2017.

Dated: January 5, 2017.

Leslie Kux,
Associate Commissioner for Policy.

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applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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.

FOR FURTHER INFORMATION CONTACT:
Emily Baker, 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, 301–796–7524, Emily.Baker@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a 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 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 response to FDA’s letters to manufacturers holding new drug applications, most manufacturers of acetaminophen-containing prescription and OTC drug products marketed under an approved application now include a warning statement on their product labels to address the risk of serious skin reactions. FDA recommends that manufacturers of all acetaminophen-containing OTC drug products (both single- and combination-ingredient acetaminophen products) marketed under the Tentative Final Monograph (TFM) for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products include in labeling the language recommended in this guidance to warn consumers that acetaminophen may cause severe skin reactions. At this time, FDA does not intend to take action against the marketing of single- and combination-ingredient, acetaminophen-containing, OTC drug products bearing the recommended allergy warning that are otherwise marketed in compliance with the TFM and applicable regulations.

In the Federal Register of November 28, 2014 (79 FR 70879), FDA published a draft guidance entitled “Recommended Warning for Over-the-Counter Acetaminophen-Containing Drug Products and Labeling Statements Regarding Serious Skin Reactions.” See: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm424898.pdf. The November 2014 draft guidance gave interested persons an opportunity to submit comments through January 27, 2015. We have made changes to the guidance in response to comments received and have added labeling information about products that contain both acetaminophen and aspirin.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the recommended warning for OTC acetaminophen-containing drug products and labeling statements regarding serious skin reactions. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the 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)).

III. 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: January 5, 2017.
Leslie Kux,
Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0067]

Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.