DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


The Drug Supply Chain Security Act Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How To Exchange Product Tracing Information: 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How To Exchange Product Tracing Information.” The draft guidance addresses the drug supply chain security provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), which requires the Secretary of the Department of Health and Human Services to establish initial standards for the interoperable exchange of transaction information, transaction history, and transaction statements, in paper or electronic format. Specifically, the guidance establishes standards for how transaction information, transaction history, and transaction statements should be exchanged among trading partners through the extension and/or use of current systems and processes.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(3)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 27, 2015. Submit either electronic or written comments concerning the

the last 3 years, we believe that OMB approval of these information collection provisions should be extended to provide for the potential future need of a firm in the dietary supplement industry to petition for an exemption from 100 percent identity testing of dietary ingredients.

Dated: November 21, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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Under section 582(b)(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


Dated: November 21, 2014.

Leslie Kux,
Associate Commissioner for Policy.
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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. 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

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