

survey to State and local health and agriculture agencies. In doing so, this team will be able to analyze the gaps and trends to occur at these respective levels which will allow FSMA counterparts to develop ways to enhance food safety and food defense. In developing these strategies, FDA will be able to work with other Federal

Agencies to improve and expand food safety and defense to ultimately reach a state of an integrated food safety system. FDA will conduct the survey electronically which allows FDA to conduct streamlines analysis while creating a low-burden, user-friendly environment for respondents to complete the survey. Once the results

have been tabulated, a report will be generated and given to FSMA section 110 to present to Congress as well as FSMA section 205(c)1 to develop the strategies to leverage and enhance current State and local capacities.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Current State and local government employees .....	1,400	1	1,400	1	1,400

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

This survey is slated to be a one-time survey. Through testing on six FDA employees who were formerly State employees, the survey development team has come to the conclusion that it should take no longer than 1 hour for the 1,400 current State and local government employees to complete the survey. FDA is requesting this data collection burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

Dated: February 17, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2012-D-0148]

**Draft Guidance for Industry on Complicated Urinary Tract Infections: Developing Drugs for Treatment; Availability**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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Complicated Urinary Tract Infections: Developing Drugs for Treatment." The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of complicated urinary tract infections (cUTIs). Specifically, this guidance addresses FDA's current thinking regarding the overall drug development program for the treatment

of cUTIs, including clinical trial designs to support approval of drugs.

**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 either electronic or written comments on the draft guidance by May 24, 2012.

**ADDRESSES:** Submit written requests for single copies of the draft 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 draft guidance document.

Submit electronic comments on the draft 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:** Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6244, Silver Spring, MD 20993-0002, 301-796-1300.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Complicated Urinary Tract Infections: Developing Drugs for Treatment." The purpose of this draft guidance is to assist sponsors and investigators in the development of drugs for the treatment of cUTIs. This draft guidance revises and replaces the draft guidance for industry entitled "Complicated Urinary

Tract Infections and Pyelonephritis—Developing Antimicrobial Drugs for Treatment" published in 1998.

Infections of the urinary tract occurring in patients with underlying functional or anatomic abnormalities of the urinary tract are defined as cUTIs. Infections of the kidney, called pyelonephritis, can occur in persons without underlying abnormalities of the urinary tract, but are also considered to be a subset of cUTI. Different types of bacteria can cause cUTI, but Gram-negative bacteria are most often associated with cUTI.

This draft guidance includes recommendations for an efficacy endpoint and noninferiority trial design. The efficacy endpoint, based on resolution of clinical symptoms and eradication of bacteria from the urinary tract, was derived from previously conducted trials for the treatment of cUTI. The draft guidance provides a scientific justification for a noninferiority margin based on historical observational data compared to the results of previously conducted clinical trials. The draft guidance also provides a discussion about patients with unmet need who have an infection caused by bacterial pathogens that show resistance to most antibacterial drugs on in vitro susceptibility testing.

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 this topic. 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. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information referred to in the guidance for clinical trial sponsors “Establishment and Operation of Clinical Trial Data Monitoring Committees” have been approved under OMB control number 0910–0581.

## III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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.

## 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: February 17, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2008–D–0610]

### Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an

Influenza Pandemic.” The guidance discusses FDA’s intended approach to enforcement of adverse event reporting requirements for drugs, biologics, medical devices, and dietary supplements during an influenza pandemic. The Agency makes recommendations to industry for focusing limited resources on reports related to products indicated for the prevention and treatment of influenza and other specific types of reports indicated in the guidance.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**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:

*Regarding pandemic influenza:* Carmen Maher, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4146, Silver Spring, MD 20993–0002, 301–796–8510.

*Regarding human drug products:* Toni Piazza-Hepp, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4480, Silver Spring, MD 20993–0002, 301–796–0520.

*Regarding human biological products:* Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

*Regarding medical device products:* Deborah Moore, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3230, Silver Spring, MD 20993–0002, 301–796–6106.

*Regarding dietary supplements:* John Sheehan, Center for Food Safety and Applied Nutrition (HFS–315), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1488.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a guidance for industry entitled “Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic.” FDA anticipates that during an influenza pandemic, industry and FDA workforces may be reduced while reporting of adverse events related to widespread use of medical products indicated for the treatment and prevention of influenza may increase, although the extent of these possible changes is unknown. The guidance discusses FDA’s intended approach to enforcement of adverse event reporting requirements for drugs, biologics, medical devices, and dietary supplements during an influenza pandemic.

The guidance provides recommendations for planning, notification, and documentation for firms that report postmarketing adverse events. The guidance recommends that each firm’s pandemic influenza continuity of operations plan include instructions for reporting adverse events and a plan for the submission of stored reports that were not submitted within regulatory timeframes. The guidance recommends that firms that are unable to fulfill normal adverse event reporting requirements during an influenza pandemic do the following:

- Document the conditions that prevent them from meeting normal reporting requirements,
- Notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when these conditions exist and when the reporting process is restored, and
- Maintain records to identify what reports have been stored.

This guidance does not address monitoring and reporting of adverse events that might be imposed as a condition of authorization for products authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360bbb–3). This guidance also does not address monitoring and reporting of adverse events as required by regulations establishing the conditions for investigational use of drugs, biologics, and devices. (See 21 CFR parts 312 and 812.)

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on postmarketing adverse event reporting for medical products and dietary supplements during pandemic influenza. It does not