

that require FDA to reevaluate safety and/or effectiveness data. The goal of this guidance is to create greater consistency in how such applications are handled by sponsors and by FDA's Center for Veterinary Medicine (CVM).

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by February 17, 2009.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Suzanne J. Sechen, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8105, e-mail: suzanne.sechen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #191 entitled "Changes to Approved NADAs—New NADAs vs. Category II Supplemental NADAs". In the past, applications for changes to approved new animal drugs may have been handled inconsistently by sponsors and the agency. Inconsistency in handling such applications has been confusing for sponsors and for CVM, particularly when reviewing and referencing the history of specific new animal drug applications (NADAs). This guidance is intended to improve consistency in the way applications for changes are handled. We believe that consistent handling of these types of applications also will help maintain clarity in the administrative record, which is an important part of protecting the public health.

When proposing a change to an approved new animal drug that may affect the safety and/or effectiveness of the drug, such changes generally must be submitted to FDA either as a new

NADA or a supplemental application to the original NADA. Category II supplemental NADAs are the type of supplement that is used to propose changes that may require a reevaluation of certain safety or effectiveness data in the parent application. Specific changes meeting the requirements for a Category II supplemental NADA are described in 21 CFR 514.106(b)(2). This guidance provides examples and makes specific recommendations about when a change to an approved NADA that requires FDA to review safety and/or effectiveness data should be submitted as a new NADA and when such a change should be submitted as a Category II supplemental NADA. In addition, the guidance addresses how to handle submissions relating to certain types of proposed changes at the investigational stage.

II. Significance of Guidance

This level 1 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.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 have been approved under OMB Control No. 0910-0032.

IV. 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a

Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/cvm> or <http://www.regulations.gov>.

Dated: December 8, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-29691 Filed 12-15-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0610]

Draft 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 draft guidance for industry entitled "Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic." The draft guidance discusses FDA's intended approach to enforcement of adverse event reporting requirements for drugs, biologics, medical devices, and dietary supplements during the Federal Government Response Stages of an influenza pandemic. The agency makes recommendations to industry for focusing limited resources on reports related to influenza-related products and other specific types of reports indicated in the draft guidance.

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 February 17, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire

Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; or the Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the 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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding pandemic influenza:

Carmen Maher, Office of Counterterrorism and Emerging Threats (HF-29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4067.

Regarding human drug products:

Solomon Iyasu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4447, Silver Spring, MD 20993-0002, 301-796-2370.

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 (HFZ-533), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240-276-3442.

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 draft 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 influenza-related products may increase, although the extent of these possible changes is unknown. This draft guidance discusses FDA's intended approach to enforcement of adverse event reporting requirements for drugs, biologics, medical devices, and dietary supplements in the event of an influenza pandemic. The draft guidance provides recommendations to permit industry to focus their limited resources on reports related to influenza-related products and other specific types of reports. The draft guidance indicates FDA's intention not to object if, during Federal Government Response Stage 5, certain required adverse event reports are not provided within the timeframes required by statute and regulation, as long as any delayed reports are then provided during Federal Government Response Stage 6.

This draft 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 act) (21 U.S.C. 360bbb-3). This draft 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 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 postmarketing adverse event reporting for medical products and dietary supplements during pandemic influenza. 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 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

III. Paperwork Reduction Act of 1995

The draft guidance explains FDA's approach to enforcement of adverse event reporting requirements for drugs, biologics, medical devices, and dietary supplements during the Federal Government Response Stages of an influenza pandemic, including an intent not to object to changes in the timing of submission of certain reports during some stages of the pandemic response. The draft guidance refers to reporting requirements found in 21 CFR 310.305, 314.80, 314.98, 600.80, 606.170, 640.73, 1271.350, and part 803. These regulations contain 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) and are approved under OMB control numbers 0910-0116, 0910-0291, 0910-0230, 0910-0308, and 0910-0543.

The draft guidance also refers to adverse event reports required under sections 760 and 761 of the act (21 U.S.C. 379aa and 379aa-1), which are addressed in two draft guidances for industry. FDA's October 15, 2007, notices of availability for those draft guidances, entitled "Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application" (72 FR 58316) and "Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act" (72 FR 58313), describe related proposed collections of information. As required by the PRA, FDA published analyses of the information collection provisions of the October 2007 draft guidances and will submit the collection of information analyses to OMB for approval prior to issuing final guidances.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/cdrh/guidance.html> or <http://www.cfsan.fda.gov/~dms/>

[guidance.html](#) or <http://www.regulations.gov>.

Dated: December 3, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–29742 Filed 12–15–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0365] (formerly Docket No. 2007D–0117)

Guidance for Industry on Orally Disintegrating Tablets; 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 “Orally Disintegrating Tablets.” The guidance provides pharmaceutical manufacturers of new and generic products with an agency perspective on the definition of an orally disintegrating tablet (ODT) and also provides recommendations to applicants who would like to designate proposed products as ODTs.

DATES: Submit written or electronic 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. Submit written comments on the 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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Frank O. Holcombe, Jr., Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–9310.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Orally Disintegrating Tablets.” The guidance provides pharmaceutical manufacturers of new and generic drug products with an agency perspective on the definition of an ODT and also provides recommendations to applicants who would like to designate proposed products as ODTs.

On April 9, 2007 (72 FR 17563), FDA announced the availability of the draft version of this guidance. The public comment period closed on June 8, 2007. The draft guidance also was discussed at an Advisory Committee for Pharmaceutical Science meeting held on July 22 and 23, 2008. A number of comments were received from the public and during the meeting, all of which the agency considered carefully as it finalized the guidance and made appropriate changes. Any changes to the guidance were minor and made to clarify statements in the draft guidance.

In an effort to develop drug products that are more convenient to use and to address potential issues of patient compliance for certain product indications and patient populations, pharmaceutical manufacturers have developed products that can be ingested simply by placing them on the tongue. The products are designed to disintegrate or dissolve rapidly on contact with saliva, thus eliminating the need to chew the tablet, swallow an intact tablet, or take the tablet with liquids. This mode of administration was initially expected to be beneficial to pediatric and geriatric patients, to people with conditions related to impaired swallowing, and for treatment of patients when compliance may be difficult (e.g., for psychiatric disorders).

As firms started developing additional products using different technology and formulations, many of these later products exhibited wide variation in product characteristics from the initial products. Because this shift in product characteristics can affect suitability for particular uses, the agency developed this guidance for industry.

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 orally disintegrating tablets. 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 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.regulations.gov>.

Dated: December 8, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–29688 Filed 12–15–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0628]

Microbiological Testing for Contact Lens Care Products; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled “Microbiological Testing for Contact Lens Care Products.” FDA is co-sponsoring the public workshop with the American Academy of Ophthalmology, the American Academy of Optometry, the American Optometric Association, and the Contact Lens Association of Ophthalmologists. The purpose of the public workshop is to discuss test method parameters for evaluating the activity of contact lens care products against *Acanthamoeba*