

Dated: December 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1434]

Draft Guidance for Industry on Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules." This guidance discusses FDA recommendations for the size, shape, and other physical attributes of generic tablets intended to be swallowed intact. FDA is concerned that these characteristics of generic drugs are too varied compared to the originator drug and could affect patient outcomes.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 10, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201,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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to 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: Debra Catterson, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 11919

Rockville Pike, Rockville, MD 20852, 240-402-3861; or Vilayat Sayeed, Center for Drug Evaluation and Research (HFD-630), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240-276-8486.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules." FDA is concerned that the differences in size, shape, and other physical characteristics between the generic and the originator could adversely affect patient outcomes. For example, studies show that tablet size can affect ease of swallowing, and generic tablets that are significantly larger than their corresponding reference drug product may be more difficult to swallow, leading to potential adverse events as well as noncompliance with treatment regimens. FDA is recommending generic manufacturers consider the size, shape, and other physical characteristics of the originator drug when developing a generic version.

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 tablet size, shape, and other physical attributes of generic solid oral dosage forms. 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. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collection of information requested in the draft guidance is covered under FDA regulations at 21 CFR 314 and approved under OMB control number 0910-0001. In accordance with the PRA, prior to publication of any final guidance document, 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 material 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 either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: December 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0928]

Draft Guidance for Industry on Recommendations for Preparation and Submission of Animal Food Additive Petitions; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice published in the **Federal Register** of Wednesday, September 11, 2013 (78 FR 55727), announcing the availability of the draft guidance for industry (GFI #221) entitled "Recommendations for Preparation and Submission of Animal Food Additive Petitions."

DATES: Submit either electronic or written comments by January 9, 2014.

ADDRESSES: Submit electronic comments 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: Sharon Benz, Center for Veterinary

Medicine (HFV-220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6864, sharon.benz@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of Wednesday, September 11, 2013 (78 FR 55727), FDA announced the availability of a draft guidance for industry (GFI #221) entitled "Recommendations for Preparation and Submission of Animal Food Additive Petitions."

Interested persons were originally given until November 12, 2013, to comment on the draft guidance.

II. Request for Comments

FDA is reopening the comment period due to the inability of some commenters to submit comments through the <http://www.regulations.gov> Web site from November 4, 2013, through November 13, 2013, because of technical difficulties at that Web site.

III. How To Submit 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>.

Dated: December 4, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2013-0950]

Information Collection Request to Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICRs) to the Office of Management and Budget (OMB), Office of Information and

Regulatory Affairs (OIRA), requesting approval of a revision to the following collection of information: 1625-0019, Alternative Compliance for International and Inland Navigation Rules—33 CFR Parts 81 through 89. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before February 10, 2014.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG-2013-0950] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT). To avoid duplicate submissions, please use only one of the following means:

(1) *Online:* <http://www.regulations.gov>.

(2) *Mail:* DMF (M-30), DOT, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001.

(3) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(4) *Fax:* 202-493-2251. To ensure your comments are received in a timely manner, mark the fax, to attention Desk Officer for the Coast Guard.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of the docket and will be available for inspection or copying at room W12-140 on the West Building Ground Floor, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find the docket on the Internet at <http://www.regulations.gov>.

Copies of the ICR(s) are available through the docket on the Internet at <http://www.regulations.gov>.

Additionally, copies are available from: Commandant (CG-612), Attn Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE., Stop 7710, Washington, DC 20593-7710.

FOR FURTHER INFORMATION CONTACT:

Contact Mr. Anthony Smith, Office of Information Management, telephone 202-475-3532, or fax 202-372-8405, for questions on these documents. Contact Ms. Barbara Hairston, Program Manager, Docket Operations, 202-366-9826, for questions on the docket.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether these ICRs should be granted based on the Collections being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collections; (2) the accuracy of the estimated burden of the Collections; (3) ways to enhance the quality, utility, and clarity of information subject to the Collections; and (4) ways to minimize the burden of the Collections on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise these ICRs or decide not to seek approval of revisions of the Collections. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG-2013-0950], and must be received by February 10, 2014. We will post all comments received, without change, to <http://www.regulations.gov>. They will include any personal information you provide. We have an agreement with DOT to use their DMF. Please see the "Privacy Act" paragraph below.

Submitting Comments

If you submit a comment, please include the docket number [USCG-2013-0950], indicate the specific section of the document to which each comment applies, providing a reason for each comment. You may submit your comments and material online (*via* <http://www.regulations.gov>), by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via www.regulations.gov, it will be considered received by the Coast Guard when you successfully transmit the