4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules; 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 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 and capsules intended to be swallowed intact. FDA is concerned that differences in these physical characteristics between generic drugs and the originator drug could affect patient outcomes.

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, 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.

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: Debra Catterson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-3861; or Vilayat Sayeed, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-9077.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a 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 a generic drug and the originator drug may affect patient compliance and acceptability of medication regimens or could lead to medication errors. For example, studies show that tablet size and shape can affect ease of swallowing; 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 that generic manufacturers consider the size, shape, and other physical characteristics of the originator drug when developing a generic version.

In the Federal Register of December 10, 2013 (78 FR 74154), this guidance was published as a draft guidance. We have carefully reviewed and considered the comments that were received on the draft guidance and have made editorial changes primarily for clarification.

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 the size, shape, and other physical attributes of generic tablets and capsules. 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

This 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 (44 U.S.C. 3501-3520). The collection of information requested in the guidance is covered under FDA regulations at 21 CFR part 314 and approved under OMB control number 0910-0001.

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: June 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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