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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0559]

2-12-09
2-13-09
J.O.

Draft Guidance for Industry on Process Validation: General Principles and Practices; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until *[insert date 30 days after date of publication in the Federal Register]*, the comment period for the draft guidance entitled "Process Validation: General Principles and Practices." FDA announced the availability of this draft guidance in the **Federal Register** of November 18, 2008 (73 FR 68431). The initial comment period closes on January 20, 2009. FDA is taking this action in response to a request for an extension of the comment period, due to the holiday season, to allow interested persons sufficient time to review this draft guidance and submit comments.

DATES: Submit written or electronic comments by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments 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*.

FOR FURTHER INFORMATION CONTACT:

Brian Hasselbalch, Center for Drug Evaluation and Research (HFD-320),

cderr2008172 FDA-2008-D-0559

NEC

Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4364, Silver Spring, MD 20993-0002, 301-796-3279; or

Grace McNally, Center for Drug Evaluation and Research (HFD-320), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4374, Silver Spring, MD 20993-0002, 301-796-3286; or

Christopher Joneckis, Center for Biologics Evaluation and Research (HFM-1), Food and Drug Administration, 5515 Security Lane, rm. 7302, Rockville, MD 20852, 301-435-5681; or

Dennis Bensley, Center for Veterinary Medicine (HFV-140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8268.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is extending the comment period on a draft guidance for industry entitled "Process Validation: General Principles and Practices." This guidance outlines the general principles and approaches that FDA considers to be appropriate elements of process validation for the manufacture of human and animal drug and biological products, including active pharmaceutical ingredients (API or drug substance). This guidance incorporates principles and approaches that all manufacturers can use in validating a manufacturing process.

FDA issued the draft guidance on November 18, 2008. The initial comment period closes on January 20, 2009. In response to a request for an extension, due to the holiday season, to allow interested persons sufficient time to review this draft guidance and submit comments, FDA has decided to reopen the

comment period until [*insert date 30 days after date of publication in the Federal Register*].

II. Comments

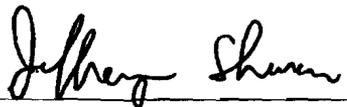
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be 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.

III. Electronic Access

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

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Dated: 2-6-09
February 6, 2009.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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