

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0525]

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Certifier [Signature]

**Supplements and Other Changes to an Approved Application; Public Meeting; Reopening of Comment Period**

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

**ACTION:** Notice; reopening of comment period.

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**SUMMARY:** The Food and Drug Administration (FDA) is reopening until May 18, 2007, the comment period for a notice of public meeting that published in the **Federal Register** of January 5, 2007 (72 FR 574). In the notice, FDA announced a February 7, 2007, meeting to solicit input on issues that the agency should consider if it decides to propose revisions to its regulations regarding chemistry, manufacturing, and controls (CMC) supplements and other changes to approved marketing applications for human drugs. FDA is reopening the comment period in light of continued public interest in this topic.

**DATES:** Submit written or electronic comments by May 18, 2007.

**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.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** David J. Cummings, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 21, rm. 3525, Rockville, MD 20993-0002, 301-796-2400, e-mail: *David.Cummings@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

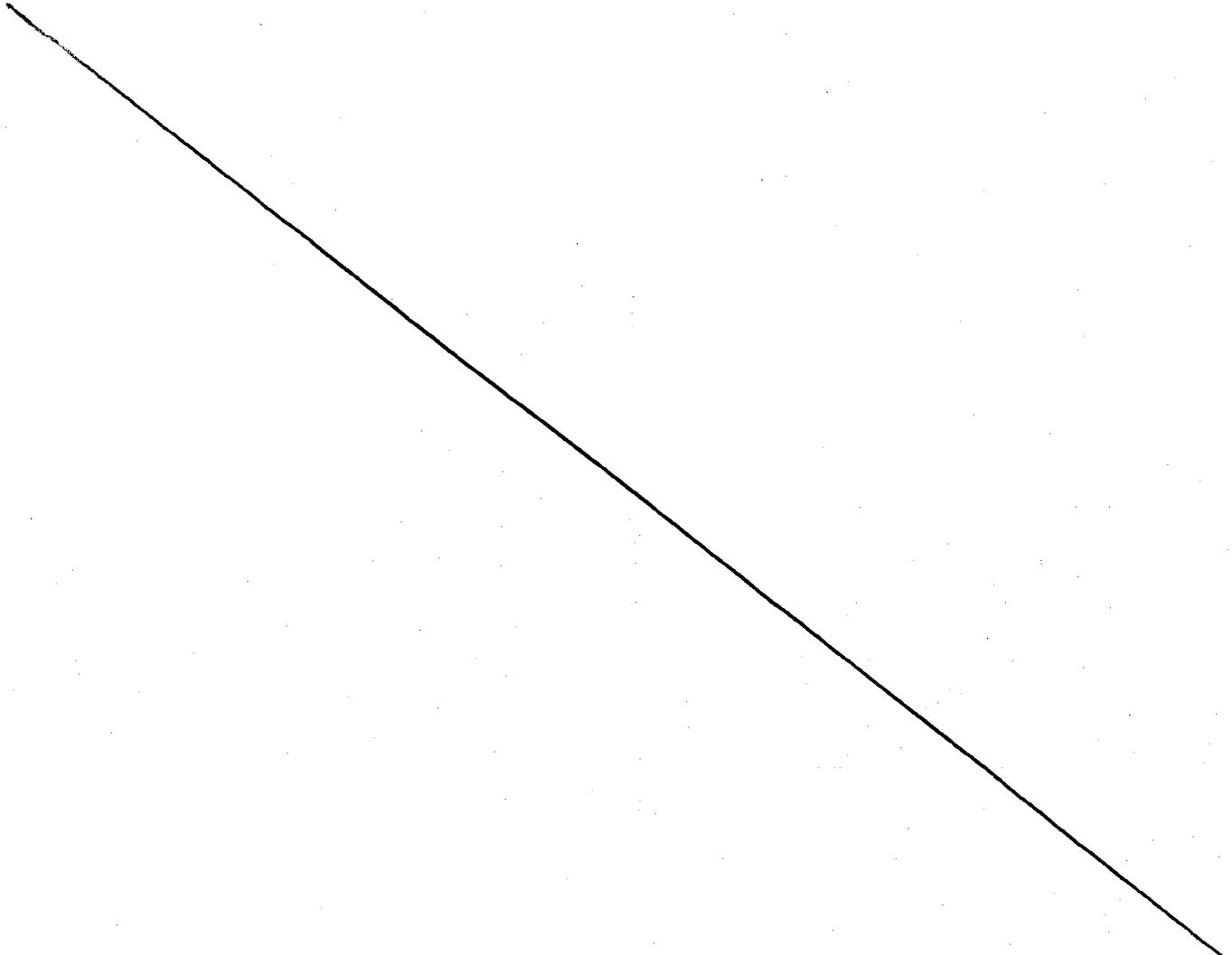
**I. Background**

On February 7, 2007, FDA held a public meeting to solicit comments on issues that FDA should consider if it decides to propose revisions to § 314.70 (21 CFR 314.70) regarding CMC supplements and other changes to approved marketing applications for human drugs. In the notice announcing the public meeting (72 FR 574), FDA stated that current § 314.70 categorizes postapproval CMC changes and their associated reporting requirements without consideration of the applicant's risk management activities or internal quality systems and practices; therefore, § 314.70 reflects a rules-based, or prescriptive, approach to regulating postapproval manufacturing changes. Current § 314.70 may create regulatory burdens and costs that discourage beneficial manufacturing changes and may not support a desirable level of innovation, modernization, and flexibility for the industry as described in FDA's pharmaceutical current good manufacturing practices for the 21st century initiative (CGMP Initiative). Consistent with the agency's risk-based approach to regulating pharmaceutical manufacturing described in the CGMP Initiative, FDA is considering possible revisions to § 314.70 to allow for more manufacturing changes to be made without prior FDA approval using a firm's internal change control system and to allow for consideration of risk-based approaches based on manufacturing process understanding, including prior knowledge of similar products, and overall quality systems to provide an enhanced risk-based approach to the CMC regulatory process.

Interested persons were given until March 7, 2007, to submit written or electronic comments to the agency related to the focus of the public meeting. As a result of continued public interest, FDA is reopening the comment period until May 18, 2007, to allow interested persons additional time to submit comments.

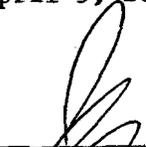
## II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments related to this topic (see **DATES**). All relevant data and information should be submitted with the written comments. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy.



Comments are to be identified with Docket No. 2006N-0525. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 4/5/07  
April 5, 2007.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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