MEMORANDUM

Date: **February 7, 2007**

To: **Interested Members of the Public**

From: **Helen Winkle**
Director, Office of Pharmaceutical Science
Center for Drug Evaluation and Research

Subject: **Public Comments on Title 21 Code of Federal Regulations Section 314.70 - *Supplements and Other Changes to an Approved Application***

The purpose of today's meeting is to solicit comments from the public on issues that FDA should consider if it develops revisions to its regulations regarding chemistry, manufacturing, and controls (CMC) supplements and other changes to approved marketing applications for human drugs covered under Title 21 Code of Federal Regulations Section 314.70 - *Supplements and Other Changes to an Approved Application.* We encourage your participation in the process to help us in our assessment of the current regulatory environment and our determination as to whether revisions to these regulations are needed to maintain the quality of pharmaceuticals for the consumer and provide for innovation and enhanced risk management strategies within the pharmaceutical industry. If you were unable to attend today's presentations, you can obtain a copy of the agenda, presentations, and transcript from the Division of Dockets Management under docket number 2006N-0525. In addition, we understand that audiovisual copies in DVD format will be available for purchase through the private company FDALive (website: http://www.FDALive.com or 301-984-0001). You may also still submit comments for consideration to the docket for FDA and public access (docket number 2006N-0525) until March 7, 2007.

For today's meeting, commenters were asked to raise relevant issues pertaining to supplements and other changes to an approved application and to respond to the following questions (see Federal Register Notice at http://www.fda.gov/OHRMS/DOCKETS/98fr/E6-22588.pdf):

1. Is it valuable for the agency to move toward a more risk-based and quality systems oriented strategy for regulating postapproval CMC changes outside of the formal application review process? What are the advantages and/or disadvantages?

2. Would revising Sec. 314.70 as described in this notice provide the same level of protection to the public as the current regulatory scheme with respect to ensuring the

safety and efficacy of human drugs? What inspectional approaches might the agency consider to evaluate manufacturing changes while ensuring public safety?

3. Would revising Sec. 314.70 as described in this notice change the regulatory burden on the pharmaceutical industry? If so, how would the burden change?

4. Would reducing the prescriptiveness of Sec. 314.70 provide manufacturers with greater regulatory flexibility? Would it encourage manufacturers to adopt CMC-related risk management strategies? Would there be disadvantages?

Subsequent to today's event, FDA will review all comments submitted to the docket, including the public presentations, and determine whether it is appropriate to propose revisions to 21 CFR 314.70. If FDA determines that revisions are appropriate, FDA will continue with its public process by publishing a Notice of Proposed Rulemaking in the Federal Register. Also, FDA may elect to hold another public meeting or workshop to solicit additional information on proposed revisions.

Again, we thank you for your interest and welcome your participation and contributions to assist FDA in its mission of ensuring that safe and effective drugs are available for the public.

FOR FURTHER INFORMATION CONTACT:
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Submit Comments to:
Division of Dockets Management (HFA-305),
Food and Drug Administration, 5630 Fishers Lane, rm. 1061,
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http://www.fda.gov/dockets/ecomments.