

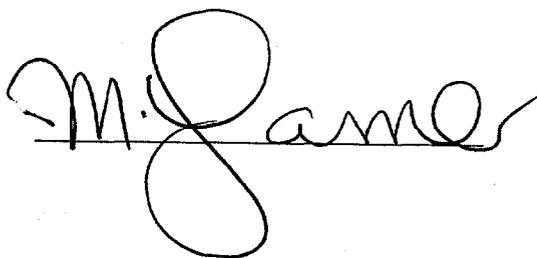
M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: February 8, 2000
To: Dockets Management Branch (HFA-305)
From: Melissa Lamb
Office of Generic Drugs
Subject: Post-Approval Changes

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation: Post-Approval Changes
Presented for: NAPM/GPIA/NPA/FDA/Fall Technical Workshop
Date Presented: 10/18/99
Presented by: Nancy B. Sager
Number of Pages: 8



Attachment

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90S-0308

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**NAPM/GPIA/NPA/FDA
Fall Technical Workshop
October 18, 1999**

Post-Approval Changes

**Nancy B. Sager
Associate Director
Office of Pharmaceutical Science, CDER**

CDER
Center for Drug Evaluation and Research



REGULATORY APPROACH

CDER's regulatory approach to post-approval CMC changes is evolving

- 21 CFR 314.70 (1985)
- SUPACs (1995 - present)
- FDAMA (1997)
- Implementation of FDAMA § 116 (now)



IMPLEMENTATION STATUS

- Draft guidance published for public comment on June 28, 1999; comment period closed August 27, 1999
- Proposed regulation published for public comment on June 28, 1999; comment period closed September 13, 1999



IMPLEMENTATION STATUS

(cont'd)

- FDA does not expect a final rule revising 21 CFR § 314.70 to be published by November 21, 1999.
- On November 21, 1999, the regulations at § 314.70 will be replaced by the provisions of section 506A.



IMPLEMENTATION STATUS

(cont'd)

- After November 20, 1999, and until the final regulation for § 314.70 publishes, section 506A will be the sole basis for FDA's regulation of post-approval manufacturing changes for products approved in NDAs or ANDAs.



IMPLEMENTATION STATUS

(cont'd)

- FDA intends to issue a final guidance on *Changes to an Approved NDA or ANDA* before November 21, 1999. The guidance will represent FDA's current thinking on how it will apply the requirements of section 506A of the Act for NDA and ANDA products.



GUIDANCE

- > 30 comment letters received
- > 1200 individual comments
- Guidance has been revised and is going through the clearance process for publication



REGULATION

- > 30 comment letters received
- ~ 300 individual comments
- Comments are under consideration