DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

SEP 25 2006

William W. Vodra
Arnold & Porter, LLP
555 Twelfth Street, NW
Washington, DC 20004-1206

Re: Docket No. 1981N-0022, Comment No. CP20
Docket No. 1976N-0052N, Comment No. CP19

Dear Mr. Vodra:

This is in reference to your citizen petition dated March 22, 2006, filed as CP20 under Docket No. 1981N-0022 and CP19 under Docket No. 1976N-0052N in the Division of Dockets Management. The petition requests that the Commissioner of Food and Drugs withdraw the Notice of Proposed Rulemaking ("NPRM") published in the Federal Register of December 22, 2005 (70 Fed. Reg. 75988). FDA proposed in the NPRM to reclassify over-the-counter nasal decongestant and weight control drug products containing phenylpropanolamine from the previously proposed Category I status (generally recognized as safe and effective) for these uses to nonmonograph status (Category II).

The procedures governing the review of citizen petitions are set out in regulations found at 21 CFR 10.30. The regulations provide, among other things, that the Commissioner shall furnish a response to a petition within 180 days of the petition, agency resources and priorities permitting. See 21 CFR 10.30(e). This tentative (interim) response is to advise you, pursuant to 21 CFR 10.30(e)(2), that because of the existence of other priorities, the Agency is unable to reach a decision on the petition at this time. We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions regarding this matter, please refer to the docket and comment numbers noted above and submit all inquiries to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Maryland 20852.

Sincerely yours,

5.25.06

Steven Galson, M.D.
Director,
Center for Drug Evaluation and Research

LETR3

1976N-0052N

MEMORANDUM

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

DATE: OCT 2 2006

FROM: Acting Director
Division of Nonprescription Regulation Development

SUBJECT: Material for Docket No. 1981N-0022 1976N-0052N

TO: Division of Docket Management, HFA-305

[X] The attached material should be placed on public display under the above referenced Docket No.

[X] This material should be cross-referenced to Comment No. ~~CP20~~ CP19

Susan S. Johnson, Ph.D.

Attachment