DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

APR 12 2007

Frederick S. Mayer, R.Ph., M.P.H.
Pharmacists Planning Service, Inc.
101 Lucas Valley Road, Suite 210
San Rafael, California 94903

1125 7 APR 13 P12:48

Re: Docket No. 2006P-0423
Comment No. CP1

Dear Mr. Mayer:

This is in reference to your citizen petition (CP1) dated September 23, 2006, received October 19, 2006, filed under Docket No. 2006P-0423 in the Division of Dockets Management. The petition requests the Commissioner of Food and Drugs to regulate labeling and packaging of acetaminophen/APAP containing products by addressing the following:

1. Mandate all non-aspirin containing over-the-counter (OTC) medicines with acetaminophen to be clearly labeled with the statement "Contains Acetaminophen. Do not take with any other Acetaminophen/APAP."
2. Regulate maximal Acetaminophen/APAP dosage and number of pills.
3. Mandate the association of Acetaminophen/APAP containing tablets with an FDA-approved MedGuide detailing the recommended dosages and possible adverse drug events of these products, including increased risks with chronic alcohol consumption.

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 is to advise you, pursuant to 21 CFR 10.30(e)(2), that because of complexities, the Agency is unable to provide a response to the petition at this time.

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,

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

2006P-0423

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MEMORANDUM

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

DATE: APR 12 2007

FROM: Acting Director
Division of Nonprescription Regulation Development

SUBJECT: Material for Docket No. 2006P-0423

TO: Division of Docket Management, HFA-305

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

☑ This material should be cross-referenced to Comment No. CP1

Susan S. Johnson, Ph.D.

Attachment