DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

DEC 8 2006

John O'Mullane, B.Sc., Ph.D.
Group Vice President, R&D
Schering-Plough Consumer Health Care
556 Morris Avenue
S-4-2 / 2170
Summit, New Jersey 07901-1330

Re: Docket No. 1978N-0038/CP18

Dear Dr. O'Mullane,

This is in reference to your citizen petition dated June 19, 2006, filed as CP18 under Docket No. 1978N-0038 in the Division of Dockets Management. Your petition requests Food and Drug Administration (FDA) take the following actions:

1. Amend the OTC sunscreen monograph to allow the combination of avobenzone and zinc oxide.
2. Permit interim marketing of products containing this combination of sunscreen active ingredients prior to publication of a new sunscreen final monograph.

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,

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

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