DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP - 9 2013

Robert Sayre, Ph.D.
President
Rapid Precision Testing Laboratories
8225 Rockcreek Parkway Cordova, TN 38016

Re: Docket No. FDA-2013-P-0323/CP1

Dear Dr. Sayre:

This is in reference to your citizen petition (CP1) dated March 15, 2013, and filed with FDA's Division of Dockets Management on March 18, 2013 (Docket No. FDA-2013-P-0323/CP1).

The petition requests that the Agency amend the monograph for Sunscreen Drug Products to reclassify the sunscreen ingredients Dioxybenzone, Oxybenzone, Trolamine Salicylate, Homosalate, and Octisalate as nonmonograph. The petition also requests to include new sunscreen testing methodology in order to prescreen products that decrease the erythemal response because you claim that they inflate SPF values that have been determined by SPF testing.

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 the existence of other priorities, 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, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research