

Food and Drug Administration
Rockville MD 20857MAR 3 3 8 4 0 '00 MAR 13 A11 :11
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Robert Monaghan
Associate Director, Regulatory Affairs
Schering-Plough HealthCare Products
110 Allen Road
PO Box 276
Liberty Corner, NJ 07938-0276

RE: Docket No. 78N-0038
Comment No. CP9

Dear Mr. Monaghan:

We refer to your citizen petition dated July 1, 1997. The petition requests the Commissioner of the Food and Drug Administration (FDA) to immediately issue a regulation prescribing a warning for cosmetic suntanning products for use in direct light. Your petition first requests that the warning for suntanning preparations proposed in § 740.19 of the tentative final monograph *q-1* (TFM) for over-the-counter (OTC) sunscreen drug products (58 FR 28195 at 28302) be strengthened to read as follows: "Warning - This product does not contain a sunscreen and does not protect against sunburn. Tanning in sunlight or under tanning lamps can cause skin cancer and premature skin aging - even if you don't burn." Your second and third requests are that this warning be finalized to take effect immediately due to public health concerns and that it be required to appear on the principal display panel (PDP). *Decision*

For the reasons given below, the agency considers action on the petition completed.

The agency discussed the warning for cosmetic suntanning products in the final rulemaking for OTC sunscreen drug products published in the Federal Register of May 21, 1999 (64 FR 27666 at 27669 and 27693) (copies of these pages enclosed). The agency required the labeling of suntanning preparations that do not contain a sunscreen ingredient (§ 740.19 (21 CFR 740.19)) to display a warning similar to that proposed in your petition, as follows: "Warning--This product does not contain a sunscreen and does not protect against sunburn. Repeated exposure of unprotected skin while tanning may increase the risk of skin aging, skin cancer, and other harmful effects to the skin even if you do not burn."

Your petition requested that the agency "immediately issue a regulation" concerning the above warning, and that it be "finalized to take effect immediately." You indicated concern that

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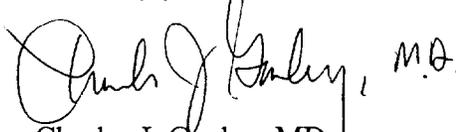
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implementation of the warning may otherwise “take several years” if it was to await finalization of a final monograph for OTC sunscreen drug products. As you know, Congress subsequently enacted the FDA Modernization Act of 1997 a few months after receipt of your petition, requiring, among other things, the issuance of regulations for OTC sunscreen products within 18 months of its enactment. While the OTC sunscreen drug product rulemaking did not require the above warning “to take effect immediately” upon publication, the agency considered this information to be sufficiently important, for safety reasons, to require a 12-month effective date as opposed to a longer effective date for the balance of the rulemaking. Also, while the agency is not requiring the warning to be displayed on the PDP, existing regulations (§ 740.2 (21 CFR 740.2)) already require such a warning to appear prominently and conspicuously on the label.

Accordingly, your first request has been granted and your second and third requests have been denied.

If you have any questions regarding the petition, please refer to the docket and comment numbers above, and submit all inquiries in triplicate, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

Sincerely yours,

A handwritten signature in black ink that reads "Charles J. Ganley, M.D." The signature is written in a cursive style with a large initial "C".

Charles J. Ganley, MD

Director

Division of OTC Drug Products

Center for Drug Evaluation and Research

Enclosure