

Citizen Petition

Final Sunscreen Monograph Labeling Claims - CARES Act HR 748

Date: April 16, 2020

The undersigned submits this petition under CFR 10.30 of the Federal Food, Drug, and Cosmetic Act for which authority has been delegated to the Commissioner of Food and Drugs to request the Commissioner of Food and Drugs to enforce labeling claims as outlined in the current May 21, 1999 final sunscreen monograph.

A. Action Requested

In compliance with the newly sign CARES Act HR 748, the following petition is being submitted by Joe DiNardo (US Citizen) who requests that the Commissioner of Food and Drugs immediately enforce the newly finalized sunscreen monograph as detailed in the CARES Act approved by the 116th Congress and signed into law by the President of the United States on March 27, 2020. This request is being made with respect to sunscreen products that are being misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act. It is the citizen's wish that this action be taken to minimize the 4.9 Million skin cancers per year reported at a cost of \$8.1 Billion in medical billing

(<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4603424/>), in addition to the 100,000 people a year that will develop melanoma that will result in 10,000 American Citizens to die annually from this preventable disease (<https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21590>).

B. Statement of Grounds

As noted in the CARES Act under Subtitle F—Over-The-Counter Drugs PART I—OTC DRUG REVIEW

TREATMENT OF SUNSCREEN DRUGS. With respect to sunscreen drugs subject to this section, the applicable requirements in terms of conformity with a final monograph, for purposes of paragraph (1)(A)(i), shall be the requirements specified in part 352 of title 21, Code of Federal Regulations, as published on May 21, 1999, beginning on page 27687 of volume 64 of the Federal Register, except that the applicable requirements governing effectiveness and labeling shall be those specified in section 201.327 of title 21, Code of Federal Regulations.

The May 21, 1999 monograph (<https://www.govinfo.gov/content/pkg/FR-1999-05-21/pdf/99-12853.pdf#page=1>) does not allow the use of any SPF values above 30 as noted in section G. Comments on Sunscreen Drug Products With High SPF Values (pg 27675) and/or §352.52 Labeling of sunscreen drug Products (pg 27688) and CFR §201.327 only states products with "SPF 15 or greater" (https://ecfr.io/Title-21/se21.4.201_1327).

Pg 27675: Therefore, the agency concludes that the label SPF declaration for sunscreens with SPF values above 30 should be limited to one collective term, which appears in § 352.50(a) of this document as follows: "For products with SPF values over 30. "SPF 30" (select one of the following: "plus" or "+"). Any statement accompanying the marketed product that states a specific SPF value above 30 or similar language indicating a person can stay in the sun more than 30 times longer than without sunscreen will cause the product to be misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act."

Pg 27688: (2) Additional indications. In addition to the indications provided in paragraph (b)(1) of this section, the following may be used for products containing any ingredient in § 352.10: (i) For products that provide an SPF of 2 to under 12 ... (ii) For products that provide an SPF of 12 to under 30 ... (iii) For products that provide an SPF of 30 or above.

The reason behind FDA's logic to restrict high SPF values is/was based on "a lack of data to correlate higher than SPF 30 sunscreen products with corresponding safety problems" (pg 27675). This statement would agree with the World Health Organization's findings summarizing skin cancer rates from "three randomized trials that showed that sunscreen use by sun sensitive subjects engaging in intentional sun exposure could increase the duration of exposure without decreasing sunburn occurrence. This increased duration could be the reason why melanoma risk is increased when sunscreen is used. Hence, sunscreen

abuse may extend sun exposure duration thus allowing sun exposure behaviours that would not be possible otherwise." (<https://www.ncbi.nlm.nih.gov/pubmed/19775356>).

There are also a variety of claims that are being made by certain sunscreen manufacturers and their associates that are not approved in the May 21, 1999 monograph or in CFR §201.327, causing sunscreens, in general, to be misbranded. These false and misleading claims are being spread to consumers via testimonies to various government officials, news stories, press releases ... etc.; for example: the American Academy of Dermatology and a few of its representatives have stated several times that there is "*no reported data of systemic, internal side effects from the use of sunscreen*" (<https://www.usatoday.com/story/news/health/2019/05/22/sunscreens-safest-environmental-working-group-2019-review/3740857002/>) the Skin Cancer Foundation claims "*sunscreen can reduce your risk of developing squamous cell carcinoma (SCC) by about 40 percent, and lower your melanoma risk by 50 percent.*" (<https://www.skincancer.org/skin-cancer-prevention/sun-protection/sunscreen/>); Companies like J&J boast that "*sunscreens safe lives*" (<https://sunsaferflorida.com>) ... etc. There is no scientific proof that any of these statements are true and in fact the World Health Organization summarized their finds on sunscreen use as "No conclusion could be drawn about the cancer-preventive activity of topical sunscreen against basal-cell carcinoma and cutaneous melanoma" (<https://www.ncbi.nlm.nih.gov/pubmed/11201401>).

In conclusion, there is no scientific evidence that supports the use of high SPF values, in fact high SPF values appear to cause the opposite effect, increasing the risk of skin cancer, not decreasing it! It is for this reason that companies need to comply with the existing May 21, 1999 monograph currently signed into law in an attempt to minimize the increase in skin cancer that has been steadily increasing since 1975 in our country despite the excessive use (annual sunscreen sales are projected to be ~\$10 Billion per year) of sunscreen products.

C. Environmental Impact

Many of the organic sunscreen actives identified in the final monograph have been reported in the scientific literature to bioaccumulate/biomagnify in the environment, contaminate the human food chain and cause a variety of toxicities to both aquatic and terrestrial species as noted in a previous submission to FDA (<https://www.regulations.gov/document?D=FDA-1978-N-0018-1508>). Although no formal environmental impact studies are being submitted with this petition, it is evident that the amount of sunscreen entering into the environment will be significantly reduced merely by the fact that less of these actives are required to achieve a product with an SPF 30 compared to products with higher values that can contain up to 45% organic sunscreens.

D. Economic Impact

Economic impact information will be submitted upon request of the commissioner. However, it should be clear that the financial impact of 10,000 citizens a year dying from melanoma is significant, plus the \$8.1 Million in medical care required to treat skin cancer, plus the economic impact of lost productivity of 5 Million people a year being treated.

Please note: The HHS study (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4603424/>) depicting overall skin cancer rates and medical cost is based on information dating back to 2011 and with the significant increases in medical costs in our country is likely a gross under estimation of current costs.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petition which are unfavorable to the petition.

(b) (6)

Joe DiNardo

(b) (6)

(Signature)

(Name of petitioner)

(Mailing address)

(Telephone number)