Personal Care Products Council
Committed to Safety, Quality & Innovation

Dockets Management
Division of Dockets Management
Food and Drug Administration
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Comments on Citizen's Petition, Docket No: FDA-2018-P-2025

To whom it may concern:

The Personal Care Products Council (PCPC)[1] appreciates the opportunity to comment on the above referenced Citizen's Petition, "Petition to Ban the Active Ingredients Oxybenzone and Octinoxate in Sunscreens and Other Personal Care Products" ("Citizen's Petition) from the Center for Biological Diversity ("Petitioners"). Our members play a major role in advancing the science of sunscreen safety and efficacy. Thus, the request to ban two critical ultraviolet filters (UV-filters), Benzophenone-3 ("oxybenzone") and octyl methoxycinnamate ("octinoxate") is of significant interest to our members.

Action Requested

While the PCPC supports the Petitioners' desire to address the global environmental phenomenon of coral bleaching, policy and regulatory decisions must be based on sound science and legal grounds. Based on the available scientific evidence and published literature, the request to ban oxybenzone and octinoxate is without scientific or legal merit.

[1] Based in Washington, DC, the Personal Care Products Council is the leading national trade association representing the global cosmetic and personal care products industry. Founded in 1894, the Council's 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the U.S. As the makers of a diverse range of products millions of consumers rely on every day, from sunscreens, toothpaste and shampoo to moisturizer, lipstick and fragrance, personal care products companies are global leaders committed to product safety, quality and innovation.

Similarly, we believe that the alternative grounds relied on by Petitioners, that the U.S. Food and Drug Administration (FDA) has not fulfilled obligations under the Endangered Species Act and the National Environmental Policy Act, are misplaced, and that the FDA is in compliance with both Acts. Accordingly, based on scientific and legal grounds, we respectfully request that the FDA deny the petition to ban the sale of sunscreen personal care products that contain the UV-filters oxybenzone or octinoxate for the reasons set forth in this Comment.

Statement of Grounds

1. Scientific Literature supports that Oxybenzone and Octinoxate are Safe and Effective Ingredients

Oxybenzone and octinoxate are safe and effective over-the-counter (OTC) sunscreen ingredients permitted for use by the FDA as UV-filters. Like all OTC drug products, sunscreens are manufactured and marketed according to the conditions set forth in the Sunscreen Monograph.[2] The monograph details the permitted active ingredients, labeling, efficacy testing, and other conditions of use, as well as other considerations. Of specific interest here, 21 C.F.R §352.10 provides the list of active ingredients, including oxybenzone and octinoxate, for sunscreen drug products. There are 16 permitted UV-filters, which function as the active ingredients in sunscreens, though practically only approximately nine of these filters are used in most commercially available products.

Oxybenzone and octinoxate have been used for decades and are found in many healthcare and personal care products on the market today, including sunscreens, lip balms, and lotions specifically designed to help adults and children guard against dangers posed by sun exposure. These ingredients are in a majority of all sunscreen products on the market today. Oxybenzone is one of the few available sunscreen UV-filters that provide effective broad-spectrum protection

[2] *See* 21 C.F.R. 352.1(a) (2018). Additionally, both ingredients are permitted for sun protection use in other areas of the world as well. Octinoxate is allowed at concentrations up to 7.5% by US FDA; up to 7.5% in Canada; up to 10% in the European Union and in Australia; and up to 20% in Japan. Oxybenzone is allowed up to 6% by US FDA; up to 6% in Canada and the European Union; up to 10% in Australia, Mexico and China; and up to 5% in Japan and Korea.

from both ultraviolet A (UVA) and ultraviolet B (UVB) rays that contribute to skin cancer. Octinoxate also plays a critical role in protecting against UVB rays and is essential in many sunscreen formulations because of its properties.

Because of this, we are deeply concerned that a policy proposal to restrict the use of these critical UV-filters as sunscreen ingredients is based on a very limited number of reports from which concrete conclusions cannot be drawn. No published study has linked exposure to oxybenzone and/or octinoxate to adverse effects on coral reef health in a native setting. Additionally, no published study has associated oxybenzone and/or octinoxate with a reduced ability of native coral reefs to respond to other environmental stressors, including rising ocean temperatures, sediment from runoff, sewage or over fishing.

With such a limited number of FDA-permitted UV-filters from which to formulate sunscreen products in the U.S., a restriction or ban of any one of the remaining UV-filters would seriously constrain manufacturers' ability to provide consumers with sunscreens that effectively protect them from harmful short-term and long-term effects of the sun, including skin cancer and early aging. In addition to the FDA, other global governmental entities have concluded that UV-filters, including oxybenzone and octinoxate, at concentrations used in currently available commercial products do not pose a risk to human health. Despite their approval by the FDA for use in OTC drugs, Petitioners allege in this Petition that oxybenzone and octinoxate are harmful to the environment and human health. This position is not supported by the majority of scientists worldwide.

a. Global Warming is the Primary Environmental Threat to Coral Reefs

Few dispute that coral and coral reefs are facing challenges. It is also widely understood that coral bleaching is the direct result of warming ocean temperatures resulting from anthropogenically-driven climate change.[3] In addition to the governmental agencies and

[3] *See* Terry P. Hughes, James T. Kerry, Mariana Álvarez-Noriega, Jorge G. Álvarez-Romero, Kristen D. Anderson, Andrew H. Baird, Russell C. Babcock, Maria Beger, David R. Bellwood, Ray Berkelmans, Tom C. Bridge, Ian R. Butler, Maria Byrne, Neal E. Cantin, Steeve Comeau, Sean R. Connolly, Graeme S. Cumming, Steven J. Dalton, Guillermo Diaz-Pulido, C. Mark Eakin, Will F. Figueira, James P. Gilmour, Hugo B. Harrison, Scott F. Heron, Andrew S. Hoey, Jean-Paul A. Hobbs, Mia O. Hoogenboom, Emma V. Kennedy, Chao-yang Kuo, Janice M. Lough, Ryan J. Lowe, Gang Liu, Malcolm T. McCulloch, Hamish A. Malcolm, Michael J. McWilliam, John M. Pandolfi,

environmental organizations that have identified rising water temperatures from global warming as the culprit for coral bleaching,[4] several leading researchers and scientists have reached a similar conclusion. For example, the Hughes *et al.* study concluded that water quality had little effect on the coral reefs, pointing instead to rising sea temperatures from global warming as the cause of coral bleaching, "[w]ater quality and fishing pressure had minimal effect on the unprecedented bleaching in 2016, suggesting that local protection of reefs affords little or no resistance to extreme heat."[5] In another *Nature* paper, Bruno and Valdivia concluded that local population density is not correlated to coral reef decline and that only concerted global action to reduce ocean temperatures can reverse coral reef decline.[6]

Furthermore, the US Environmental Protection Agency (EPA), together with the U.S. Coral Reef Task Force (USCRTF), a network of field and laboratory scientists, coral reef managers and federal agency representatives co-chaired by the National Oceanic and Atmospheric Administration and the Department of the Interior with regular participation from twelve federal agencies, seven states and territories, and three freely associated states, have indicated that climate change and ocean acidification due to CO2 absorption present the most intense global threats to coral reefs. The scientific consensus of these organizations is as more carbon dioxide is released into the atmosphere from climate change, about one-third is absorbed into the world's oceans. This CO2 reacts with sea water to form carbonic acid which causes the ocean to become more acidic. The ocean is now 30 percent more acidic than it was before the

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Rachel J. Pears, Morgan S. Pratchett, Verena Schoepf, Tristan Simpson, William J. Skirving, Brigitte Sommer, Gergely Torda, David R. Wachenfeld, Bette L. Willis & Shaun K. Wilson. 2017. Global warming and recurrent mass bleaching of corals. *Nature* 543: 373–377. doi:10.1038/nature2170; *See also:*
-- National Oceanic and Atmospheric Administration (NOAA): https://oceanservice.noaa.gov/facts/coral_bleach.html;
--Australia's Great Barrier Reef Marine Park Authority: http://www.gbrmpa.gov.au/managing-the-reef/threats-to-the-reef/climate-change/what-does-this-mean-for-species/corals/what-is-coral-bleaching
--The Nature Conservancy: https://www.nature.org/ourinitiatives/urgentissues/oceans/coral-reefs/coral-reefs-coral-bleaching-what-you-need-to-know.xml;
--National Aeronautics and Space Administration (NASA): https://earthobservatory.nasa.gov/IOTD/view.php?id=88057.
(Pages accessed January 2018.)

[4] *Supra,* at footnote 1.

[5] *Hughes, supra*, at footnote 3 (373-377); *see also* Rodgers, K.S., Bahr, K.D., Jokiel, P.L., Donà, A.R. 2017. Patterns of bleaching and mortality following widespread warming events in 2014 and 2015 at the Hanauma Bay Nature Preserve, Hawai`i. *Peer J*, 5: e3355 ("…[R]esults suggest that elevated temperature was more influential in coral bleaching and the associated mortality than high circulation or visitor use.")

[6] Bruno, J.F. and Valdivia, A. 2016. Coral reef degradation is not correlated with local human population density. *Scientific Reports.* doi: 10.1038/srep29778.

industrial revolution. This is the single biggest change in ocean chemistry in the last 50 million years. According to EPA, approximately 525 billion tons of CO2 have already been absorbed into the world's oceans and about 22 million tons are added every single day.[7]

Further, as indicated by the United Nations Educational, Scientific and Cultural Organization (UNESCO) World Heritage Centre global coral mass bleaching is caused by rising water temperatures associated with climate change. It only takes a spike of 1-2°C to cause bleaching, and carbon emissions have caused a 1°C increase in global surface temperature since pre-industrial times. According to UNESCO, bleaching and mortality of corals due to heat stress, resulting from global warming and observed over the past three decades, is expected to continue and intensify in the coming decades unless CO2 emissions are drastically reduced.[8]

Unfortunately, Petitioners have largely ignored the scientific weight of evidence and scientific findings established by these credible organizations, and have instead seized upon the work of a single *in-situ* laboratory scientific study (Downs *et al.* (2016[9])) which alleged adverse impacts of oxybenzone to corals.[10] Indeed, the results from this laboratory study were those that the Hawaii State Legislature primarily relied upon in passing SB 2571.[11] Additionally, we are deeply concerned that results of a non-validated and non-standardized *in-vitro* cell line assay, as featured in Downs *et al.* (2016), were used to derive a toxicity threshold for native Hawaiian coral species, such as *P. damicornis*. We also question the validity of deriving whole organism

[7] *See generally* The EPA Blog: Coral Reefs (Sept. 17, 2014), *available at* https://blog.epa.gov/2014/09/17/coral-reefs/.

[8] Heron et al. 2018. Impacts of Climate Change on World Heritage Coral Reefs: Update to the First Global Scientific Assessment. Paris, UNESCO World Heritage Centre, *available at* https://www.icriforum.org/sites/default/files/265625e.pdf.

[9] Downs CA, Kramarsky-Winter E, Segal R, Fauth J, Knutson S, Bronstein O, Ciner FR, Jeger R, Lichtenfeld Y, Woodley CM, Pennington P, Cadenas K, Kushmaro A and Loya Y. Toxicopathological effects of the sunscreen UV filter, Oxybenzone (Benzophenone-3), on coral planulae and cultured primary cells and its environmental contamination in Hawaii and the US Virgin Islands, *Arch. Environ. Contam. Toxicol*. (2016) 70, 2, 265 – 288.

[10] The study tested coral under laboratory conditions and extrapolated the findings to identify risk, based only on a cursory monitoring of oxybenzone in marine waters.

[11] Among other shortcomings, SB 2571 discounted the vast amount of historical data found within the Pacific Islands Ocean Observation System, managed by the University of Hawaii: http://www.pacioos.hawaii.edu/projects/coral/. In this system, it is clear that coral presence, density and ecological status are based on habitat type and quality. Relating coral ecological status is dependent upon these factors first, then the potential presence and intensity of other factors, including temperature, currents and changes in water quality. Without taking these factors into account, bans of any chemical may have no positive ecological change.

toxicity thresholds from short-term ecotoxicity experiments using isolated cells *in-vitro*.

Further, in the same Downs *et al.* study (2016), eco-toxicological studies were also conducted on coral larvae (planula) (24 hour LC_{50} = 139 µg/L; 24 hour planulae deformity EC_{50} = 49 µg/L), although it recently has been suggested that adult coral may be the most sensitive coral life-stage to test eco-toxicological effects of benzophenones (He *et al*., 2018).[12] Additionally, the species tested by Downs *et al*. (2016) in their *in-vivo* tests is not native to Hawaiian Pacific waters, meaning the findings of Downs *et al*. (2016) are of questionable relevance to establishing the hazard of oxybenzone to US-Pacific coral species. The results of *in-vivo* coral eco-toxicological tests are certainly more suitable for deriving coral eco-toxicity thresholds than *in-vitro* cell line assays, but we are extremely concerned that a reliable dose response relationship could not be demonstrated due to data inconsistency issues (Schaap & Slijkerman, 2018).[13] Additionally, lack of analytical support during eco-toxicity tests by Downs *et al*. (2016) and subsequent reliance on basing eco-toxicological thresholds on nominal oxybenzone concentrations make the results of Downs *et al*. (2016) extremely unreliable and unsuitable for coral hazard assessment.

More recently, He *et al*. (2018)[14] investigated the effects of oxybenzone on the hard coral species *S. damicornis*. *S. damicornis* is native to Hawaii (and the Pacific region) and can therefore be considered a more relevant test species for US-Pacific regions than the Red Sea species (*S. pistillata*) that was studied by Downs *et al*. (2016). He *et al*. (2018) investigated the effects of oxybenzone on several lethal and sub-lethal end-points using adult coral fragments and planula. Both adult and larval coral LC_{50}s (concentration of chemical required to kill 50% of organisms) were above 1,000 µg/L. Effects on larval settlement adult and larval bleaching were only observed at an EC_{50} (concentration of a chemical required to cause half-maximal effects) of 1000 µg/L oxybenzone and above. Accordingly, given that He *et al.* observed negative effects on the tested adult and larval *S. damicornis* only at relatively high concentration levels of

[12] He, T., Tsui, M.M.P., Tan, C.J., Ng, K.Y., Guo, F.W., Wang, L.H., Chen, T.H., Fan, T.Y., Lam, P.K.S., Murphy, M.B. 2018. Comparative toxicities of four benzophenone ultraviolet filters to two life stages of two coral species. *Science of the Total Environment* 651 (2): 2391-2399.
[13] Schaap, I., Slijkerman, D.M.E. 2018. An environmental risk assessment of three organic UV-filters at Lac Bay, Bonaire, Southern Caribbean. *Marine Pollution Bulletin* 135: 490-495.
[14] He, T., *Science of the Total Environment*, 2391-99.

oxybenzone, it is safe to say that all life stages of the Indo-Pacific hard coral species *S. damicornis* are relatively insensitive to oxybenzone exposure.

Additionally, there are currently very limited published coral eco-toxicological data for octinoxate. In a 2008 study by Danovaro *et al*.[15], *in-situ* experiments were conducted to examine the effects of sunscreen ingredients (including oxybenzone and octinoxate) and some sunscreen finished products on coral obtained from 4 separate areas (Atlantic, Indian, and Pacific Oceans, and the Red Sea). The study exposed coral species to sunscreens concentrations (10, 33, 50, and 100 µL/L seawater) that are several orders of magnitude above reported environmental concentrations of these materials and corals were dosed by sealing corals in plastic bags containing sunscreens. We have huge concerns over this method and question the environmental relevance of this approach. Danovaro *et al*. (2008) concluded that "[a]fter the addition of sunscreens, viral abundance in seawater surrounding coral branches increased significantly …". However, it should be noted that correlation does not amount to causation. Additionally, it should be noted that the authors were unable to show a dose response of coral to octinoxate and oxybenzone. This makes it impossible to use the results of Danovaro *et al*. (2008) to adequately assess the environmental hazard of oxybenzone and octinoxate to the coral species that were studied.

He *et al*. (2018) cite another study that has recently been submitted for publication (by the same authors) showing that *S. damicornis* is even more insensitive to octinoxate than benzophenones. Given the relatively low sensitivity of *S. damicornis* to benzophenones, it is likely that octinoxate exerts similarly minor eco-toxic effects to the US-Pacific coral species *S. damicornis.*

Also, a recent environmental monitoring study was conducted which examined Hawaiian coastal waters, sediment, and coral tissue. The study was led by Dr. Carys Mitchelmore,

[15] Danovaro, R., Bongiorni, L., Corinaldesi, C., Giovannelli, D., Damiani, E., Astolfi, P., Greci, L., Pusceddu, L. 2008. Sunscreens cause coral bleaching by promoting viral infections. *Environmental Health Perspectives* 116 (4):441-7.

University of Maryland Center for Environmental Sciences[16]. In this study, oxybenzone concentrations in the ng/L range were detected. In addition, no quantifiable octinoxate concentrations could be detected (limited of quantification, LOQ = 5 ng/L). A manuscript outlining this work has been submitted for publication and is currently undergoing peer review. We believe this investigation is a more comprehensive and technically superior environmental monitoring study than was the study conducted by Downs *et al*. (2016). In particular, Dr. Mitchelmore's study sampled a greater number of sites and sub-sites around the Island of Oahu, Hawaii and employed a high degree of analytical replication compared to Downs *et al*. (2016). Dr. Mitchelmore's team measured oxybenzone concentrations of 0.2-136 ng/L (analytical limit of detection, LOD = 5 ng/L). We are, however, concerned that Downs *et al*. (2016) detected oxybenzone at a concentration of 19,000 ng/L at a single site, while oxybenzone concentrations at 6 adjacent sites were below their analytical LOD of 5 µg/L. Moreover, we have significant concerns that too few sites were sampled, sub-sites were not sampled, and a sufficient degree of analytical replication was not undertaken by Downs *et al*. (2016).

Other recent environmental monitoring studies have noted temporal and spatial (including seasonal) fluctuations in UV-filter ingredient concentrations in ocean waters (Tsui *et al*., 2014, Bargar *et al*., 2015; Tsui *et al*., 2017).[17] However, it is clear that typical concentrations of UV-filter ingredients detected in coastal waters are in the ng/L to low µg/L range, as stated by a recent 2018 briefing report on the impacts of sunscreens on coral reefs conducted by the International Coral Reef Initiative (ICRI). The only single exception is the 1.395 mg/L oxybenzone reported in the US Virgin Islands (Downs *et al*., 2016), although we believe this should be considered as a dramatic outlier when compared to all published data. Typical

[16] The Personal Care Products Council provided Dr. Carys Mitchelmore with a research grant through the University of Maryland.

[17] *See* Tsui, M.M.P., Lam, J.C.W., Ng, T.Y., Ang, P.O., Murphy, M.B., Lam, P.K.S. 2017. Occurrence, distribution, and fate of organic UV filters in coral communities. *Environmental Science and Technology* 51: 4182–4190; Tsui, M.M.P., Leung, H.W., Lam, P.K.S., Murphy, M.B. 2014a. Seasonal occurrence, removal efficiencies and preliminary risk assessment of multiple classes of organic UV filters in wastewater treatment plants. *Water Research* 53: 58–67; Bargar, T.A., Alvarez, D.A., Garrison, V.H. 2015. Synthetic ultraviolet light filtering chemical contamination of coastal waters of Virgin Islands national park, St John, US Virgin Islands. *Marine Pollution Bulletin* 101 (1): 193–199.

published UV filter levels in the marine environment are therefore more comparable with the concentrations detected by Dr. Mitchelmore in Hawaii.

Given the extensive environmental sampling and analytical rigor employed by Dr. Mitchelmore's research team compared to that of Downs *et al*. (2016), we feel that it is prudent to compare published *in-vivo* eco-toxicological data for Hawaiian coral species (generated by He *et al*., 2018) with the results of this investigation to provide an insight into the environmental risk posed by oxybenzone. When these eco-toxicological and environmental monitoring data are compared, Dr. Mitchelmore's worst case measured oxybenzone concentration (136 ng/L) is 7,353 times lower than He *et al*. (2018)'s lowest oxybenzone EC_{50} and LC_{50} of 1,000 and >1,000 µg/L (1,000,000 and >1,000,000 ng/L), respectively. Despite huge concerns existing over data quality, when Dr. Mitchelmore's measured worst case environmental oxybenzone concentration is compared with Downs *et al*. (2016)'s *in-vivo* planula LC_{50} and EC_{50} values (139,000 and 49,000 ng/L, respectively), this concentration is still 1,022 and 360 times lower than these toxicity thresholds, respectively. Even comparing Downs *et al*. (2015)'s lowest 4 hour *in-vitro* cell-line LC_{50} value (8,000 ng/L) with Dr. Mitchelmore's highest measured oxybenzone concentration suggests an acceptable environmental risk of oxybenzone, with measured values being 49 times lower than Downs *et al*. (2016)'s lowest cell-line LC_{50} value.

Finally, the FDA's Environmental Assessment of Human Drug and Biologics Applications Guidance for Industry states that, "the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion (ppb)" and will be excluded from environmental impact review. Both oxybenzone and octinoxate concentrations detected by Dr. Mitchelmore's study were in the part per trillion range; an order of magnitude lower than the value that the FDA consider to be of concern.

b. The Scientific Evidence Does Not Support that Oxybenzone and Octinoxate are Detrimental to Human Health

We disagree with the Center for Biological Diversity's conclusion that oxybenzone or octinoxate disrupt endocrine function in humans. Presently, the preponderance of scientific

evidence does not conclude that there are adverse effects resulting from exposure to either oxybenzone or octinoxate, both of which have an extensive history of use.

The National Toxicology Program division of the U.S. National Institutes of Environmental Health completed studies looking at "endocrine disruption" by either octinoxate or oxybenzone in 2011-2012. The findings indicated that following oral administration of octylmethoxycinnamate (octinoxate) or oxybenzone, neither compound demonstrated estrogenic or androgen agonist/antagonist activity up to the limit dose level of 1000 mg/kg.[18] Both octinoxate and oxybenzone were included in a review focused on potential estrogenic effects conducted by the European Commission (EC) independent scientific experts, i.e., the Scientific Committee on Cosmetic and Non-Food Products (SCCNFP). The review concluded that "…the SCCNFP is of the opinion that the organic UV-filters used in cosmetic sunscreen products, allowed in the EU market today, have no estrogenic effects that could potentially affect human health."[19] Witorsch and Thomas (2010)[20] undertook a comprehensive review of personal care products and endocrine disruption. Regarding UV filters, the authors concluded [t]o date, no human data exist to suggest that UV filters evoke endocrine disruptive effects, although it appears unlikely in view of the high doses required to produce effects under laboratory conditions."

Thus, as stated above, there is no scientific merit to restricting or banning oxybenzone and octinoxate based on either concerns about the environment or human health. Accordingly, we respectfully request that the FDA deny the request to ban oxybenzone and octinoxate from use in sunscreens and personal care products.

2. **FDA is in Compliance with the Endangered Species Act**

[18] *See* http://ntp.niehs.nih.gov/testing/status/agents/ts-m20239.html and https://ntp.niehs.nih.gov/testing/status/agents/ts-10260-s.html (Note: the full report and its data can be requested through the relevant and applicable public disclosure statutes).
[19] Opinion on the Evaluation of Potentially Estrogenic Effects of UV-Filters, adopted June 12, 2001, http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/sccnfp_opinions_97_04/sccp_out145_en.htm.
[20] Witorsch, R.J. and Thomas, J.A. (2010) Personal care products and endocrine disruption: A critical review of the literature. *Critical Reviews in Toxicology*, 40:1-30.

Petitioners argue that even if the FDA were to deny their request to ban oxybenzone and octinoxate, FDA is itself not in compliance with the Endangered Species Act or the National Environmental Policy Act. This is incorrect.

The Endangered Species Act (ESA) provides for the conservation of critical species by utilizing the "best scientific and commercial data available"[21] to determine whether federal agency actions may affect listed species or critical habitat. Under Section 7 of the ESA, federal agencies fulfill their obligations by engaging with the National Marine Fisheries Service (NMFS) or the United States Fish and Wildlife Service (FWS) (collectively "the Services") if required. Specifically, the ESA requires that each federal agency consult with FWS or the NMFS to ensure that any action authorized, funded, or carried out by that agency is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of critical habitat for such species.[22] Under the ESA and its implementing regulations, a federal agency must engage in formal consultation with the Services if an action undertaken by that agency "may affect" an endangered or threatened species or its critical habitat.[23]

There are three main threshold criteria that are necessary to trigger an analysis under Section 7 of the ESA. First, there must be some type of qualifying agency action by the federal agency. Second, the ESA only applies to those species or critical habitats that are listed as threatened or endangered under the ESA. Finally, there needs to be a determination that the action proposed by the relevant federal agency "may affect" an endangered or threatened species or its critical habitat. Thus, the analysis of whether or not a consultation is required under the ESA is more complex than the picture Petitioners paint, and we believe is ultimately not necessary.

a. The relevant "agency action" occurred years before the first two coral species were listed under the ESA, and decades before any research alleged a link between UV filters and coral health

[21] 16 U.S.C. § 1536(a)(2 (2018).
[22] *See id.*
[23] 50 C.F.R. § 402.14(a) (2018).

To trigger ESA requirements, an agency must have engaged in an agency action.[24] "Agency action" is defined by the ESA as "any action authorized, funded, or carried out by" a federal agency.[25] Wildlife and Fisheries regulations that outline the formal consultation process indicate that "each federal agency shall review at the earliest possible time to determine whether any action may affect listed species or critical habitat."**[26]** We submit that the relevant agency action taken by FDA was its issuance of its final rule regarding sunscreens in 1999 (the "Final Sunscreen Rule")[27] in which FDA outlined, among other things, the active ingredients, including oxybenzone and octinoxate that are permitted for use in OTC sunscreen drug products.

The Final Sunscreen Rule was stayed indefinitely shortly after its issuance in 1999. To date, the stay has not been lifted, and based on recent indications from FDA it is feasible that a new proposed Tentative Final Monograph might soon be issued.[28] Though Petitioners are correct that a 2011 sunscreen rulemaking references oxybenzone, the reference largely occurs in the context of "two sunscreen standards for use in SPF testing,"[29] one of which utilizes oxybenzone as an ingredient. As FDA makes clear in the summary, the 2011 Rule addresses concerns about labeling and testing, but does "not address issues related to sunscreen active ingredients or certain other issues regarding the GRASE determination for sunscreen products."[30] Similarly, we disagree with Petitioners that the intervening sunscreen rulemakings were "reauthorizations" of the active ingredients given that the rulemakings explicitly stated that FDA was not addressing the GRASE status of the active ingredients. As such, the Sunscreen Final Rule should be considered the operative agency action.

b. <u>The relevant listed species (i.e. coral life) were not identified as endangered at the time of the agency action</u>

[24] 16 U.S.C. § 1536(a)(2) (2018); *see also* 50 C.F.R. § 402.03 (2018) (stating that the consultation requirement in Section 7 of the ESA is limited to agency "action in which there is discretionary Federal involvement or control").
[25] 16 U.S.C. § 1536(a)(2) (2018).
[26] 50 C.F.R. § 402.14(a) (2018).
[27] *See* Sunscreen Drug Products For Over-The-Counter Human Use; Final Monograph, 64 Fed. Reg. 98, 27666 (May 21, 1999) (to be codified at C.F.R. pts. 201, 310, and 352).
[28] *See* Unified Agenda of Regulatory and Deregulatory Actions Active Regulatory Actions Listed by Agency: Sunscreen Drug Products for Over-the-Counter Human Use; Tentative Final Monograph, *available* at https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201810&RIN=0910-AF43C.
[29] Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use, 76 Fed. Reg. 117, 35620, 35646 (June 17, 2011) (to be codified at C.F.R. pts. 201 and 310).
[30] *Id.* at 35260.

Any obligations under Section 7 of the ESA only arise to the extent there is a listed species at issue at the time the relevant agency action is taken. It is therefore critical to any analysis under section 7 of the ESA to understand when the specific species, in this case coral, were listed as either threatened or endangered relative to FDA's issuance of the Final Sunscreen Rule. Petitioners frequently cite two ESA threatened coral species, Elkhorn (*Acropora palmata*) and Staghorn (*Acropora cervicornis*), throughout their petition to ban oxybenzone and octinoxate. Both Elkhorn and Staghorn coral were listed under the Endangered Species Act several years after the 1999 Sunscreen Final Rule was issued. A final rule was published in 2006 to list Elkhorn (*Acropora palmata*) and Staghorn (*A. cervicornis*) corals as threatened species under the Endangered Species Act (ESA) of 1973, as amended.[31] Subsequently in 2014, the National Marine Fisheries Service published a final rule determining that these two species (*Acropora cervicornis* and *Acropora palmata*) still warranted listing as threatened.[32] Again, both these rules were published years after the Final Sunscreen Rule.

Accordingly, Section 7 of the ESA could not have been triggered at the time FDA was considering oxybenzone and octinoxate as permitted active ingredients.

c. <u>The ESA does not mandate formal consultation unless a "may affect" determination is made</u>

Whether and when a species is listed is a central prerequisite for any analysis under the Endangered Species Act, but it is not the end of the inquiry. The next step in the analysis is to consider whether the "best scientific and commercial data available"[33] in 1999 would indicate that the agency's action (i.e., an FDA finding on active ingredients) on the listed species (i.e. coral) would be detrimental. We submit that FDA, after considering all scientific and commercial data available, could not have reasonably determined that issuance of the Final Sunscreen Rule

[31] Endangered and Threatened Species: Final Listing Determinations for Elkhorn Coral and Staghorn Coral, 71 Fed. Reg. 81, 26852(May 9, 2006) (to be codified at C.F.R. pt. 223)(emphasis added)).
[32] Endangered and Threatened Wildlife and Plants: Final Listing Determinations on Proposal To List 66 Reef-Building Coral Species and To Reclassify Elkhorn and Staghorn Corals, 79 Fed. Reg. 175, 53852 (September 10, 2014) (to be codified at C.F.R. pt. 223).

[33] *See* 16 U.S.C. § 1536 (a)(2) (2018).

met or exceeded the "may affect coral life" threshold requirement to trigger an inter-agency consultation under Section 7 of the ESA.

Section 7 of the ESA provides that "each federal agency shall, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence of any endangered species."[34] However, the implementing regulations, codified at 50 C.F.R. § 402.14(a) require that agencies review their actions to "to determine whether any action *may affect* listed species or critical habitat. *If* such a determination is made, formal consultation is required, except as noted in paragraph (b) of this section" (emphasis added). Use of the words "may" and "if" underscore that mere listing of a species under the Endangered Species does not automatically trigger the consultation process. Rather, the consultation process is only triggered "*if* a" determination that an action "*may affect"* a listed species is made. The determination of possible effects and the decision whether consultation is required rests with the federal agency proposing the action i.e. "the action agency", and not with either the NMFS or the FWS.[35] Similarly, consultation is not necessarily required simply because there is *some* identifiable impact on the listed species. Were this the inquiry, it would be difficult to envision a scenario that would ever pass muster under Section 7 of the ESA since by definition "listed species" are in some state of peril and some effect would almost always be found. Rather, the operative inquiry is whether the agency action itself, in this case the publication of the Sunscreen Final Rule, "will *cause* some *new* jeopardy."[36]

Further, even if the NMFS or FWS did request that the action agency enter into formal consultation, "nothing in the regulations mandates the action agency to enter into consultation after it receives such a request" as the action agency makes the final decision on whether consultation is required."[37] Therefore, if the action agency determines that its proposed action

[34] *Id*.
[35] Defenders of Wildlife v. Flowers, 414 F.3d 1066, 1070 (9th Cir. 2005).
[36] National Wildlife Federation v. National Marine Fisheries Service, 524 F.3d 917, 930 (9th Cir. 2008) (emphasis in original)).
[37] *Id*. at 1069-70.

will have "no effect" on a listed species, it is not obligated to formally consult with the National Marine Fisheries Service or Fish and Wildlife Service.[38]

This then raises the question of how an agency makes the "no effect" determination. To do so, the action agency should consider whether the "best scientific and commercial data available"[39] indicate that the effects of the agency's action would be detrimental. We submit that no such information existed as of 1999, around the time the Sunscreen Final Rule was being considered. Indeed, in 2009, the Center for Biological Diversity, the very same organization which petitions FDA in this matter, had the opportunity to raise any potential threat oxybenzone or octinoxate posed to coral reefs in its 2009 Citizen Petition requesting NMFS to list 83 coral species under the Endangered Species Act[40] (the "2009 ESA Petition"). The Center for Biological Diversity, however, did not do so in such petition, despite listing several other threats to coral species as part of an analysis of the topic.[41]

Moreover, even a general discussion of sunscreens or UV-filters is completely absent from the Center for Biological Diversity's 2009 ESA Petition.[42] Instead, the 2009 ESA Petition broadly identifies the following threat factors:

1. Anthropogenic Greenhouse Gas Emissions Resulting in Climate Change and Ocean Acidification that Threaten the Petitioned Coral Species
2. Observed and Projected Climate Change and Ocean Acidification
3. The Impacts of Climate Change and Ocean Acidification on Corals

[38] *See Pac. Rivers Council v. Thomas*, 30 F.3d 1050, 1054 (9th Cir. 1994); *see also* Inst. for Fisheries Res. v. Burwell, Case No: 16-CV-01574-VC (N.D. Cali. Aug. 30, 2016) (granting motion to dismiss claims under the Endangered Species Act).
[39] *See* 16 U.S.C. § 1536 (a)(2) (2018).
[40] *See* Endangered and Threatened Wildlife; Notice of 90-Day Finding on a Petition to List 83 Species of Corals as Threatened or Endangered Under the Endangered Species Act (ESA), 75 Fed. Reg. 27, 6616 (Feb. 10, 2010)*; see also* PETITION TO LIST 83 CORAL SPECIES UNDER THE ENDANGERED SPECIES ACT, Center for Biological Diversity (available at: https://www.biologicaldiversity.org/species/invertebrates/staghorn_coral/pdfs/Coral%20petition_10-20-09.pdf).
[41] *See* Endangered and Threatened Wildlife; Notice of 90-Day Finding on a Petition to List 83 Species of Corals as Threatened or Endangered Under the Endangered Species Act (ESA), 75 Fed. Reg. 27, 6616 (Feb. 10, 2010)*; see also* PETITION TO LIST 83 CORAL SPECIES UNDER THE ENDANGERED SPECIES ACT, Center for Biological Diversity (available at: https://www.biologicaldiversity.org/species/invertebrates/staghorn_coral/pdfs/Coral%20petition_10-20-09.pdf);
[42]*See* Petition to List 83 Coral Species Under the Endangered Species Act, Center for Biological Diversity (October 20, 2009) available at https://www.fpir.noaa.gov/Library/PRD/Coral/83%20spp%20coral%20petition%2010-20-09.pdf.

4. Greenhouse Gases Emissions Must Be Reduced to Less than 350 ppm CO2 To Protect the Petitioned Coral Species
5. Dredging
6. Coastal Development
7. Coastal Point Source Pollution
8. Agricultural and Land Use Practices
9. Disease and Predation

Each of these separate categories are broken down into further subparts and addresses causes like reef fishing, aquarium trade of corals, and oil and gas development to name a few.[43] When the National Marine Fisheries Service responded to the 2009 ESA Petition, it took into account not only the threats outlined in the 2009 ESA Petition, but also any comments submitted by the public which might bring to light further threats to coral life. Tellingly, neither the 2010 NMFS Proposed Rule[44] nor the 2014 NMFS Final Rule[45] references sunscreens, UV-filters, or oxybenzone and octionxate as threats to coral life.

It is clear then that at least in 2014, the consensus as to the factors impacting the health of coral species and coral reefs did not include a belief that sunscreens or their active ingredients were harmful. Thus, the Downs *et al.* (2016) study, which is the primary research relied upon by Petitioners here and state legislators in Hawai'i, is arguably one of the first pieces of published research to allege a link between coral health and UV-filters. Additionally, while we believe that there are significant shortcomings in the Downs *et al.* (2016) study, even if one were to assume its complete validity, the study was only published recently, years after the Final Sunscreen Rule was considered and published.**[46]** It strains logic then for Petitioners to claim that FDA has been in violation of the Endangered Species Act when there has not been FDA agency action on the sunscreen monograph subsequent to either the 2014 NMFS Final Rule or publication of the *Downs* study.

[43] *See generally id.*
[44] Finding on a Petition to List 83 Species of Coral as Threatened or Endangered, 75 FR 6616.
[45] Final Listing Determinations on Proposal To List 66 Reef-Building Coral Species and To Reclassify Elkhorn and Staghorn Corals, 79 FR 53852 (Sept. 10, 2014).
[46] C. A. Downs et al., *Toxicopathological Effects of the Sunscreen UV Filter, Oxybenzone (Benzophenone-3), on Coral Planulae and Cultured Primary Cells and Its Environmental Contamination in Hawaii and the U.S. Virgin Islands,* 70 ARCHIVES ENVTL. CONTAMINATION & TOXICOLOGY 265 (2016).

As set forth already herein and by Petitioner's themselves in the 2009 ESA Petition, the overwhelming scientific evidence points to causes like global warming and over-fishing as the causal agents of coral decline. By contrast, the evidence pointing towards oxybenzone and octinoxate is scant today and was non-existent in 1999. On this basis, FDA could not conclude issuance of the Final Sunscreen Rule in 1999 could have any effect on coral, and would be hard-pressed to make such determination today as well, even if FDA considers Downs *et al*. 2015.

Finally, if FDA were to implement the restriction or ban sought by Petitioners here, that action alone would not address the very real threats to coral that Petitioners themselves have previously identified. Similarly, continued use of sunscreens with oxybenzone or octinoxate would not "tip [coral] from a state of precarious survival into a state of likely extinction."[47] Consequently, there are reasonable grounds for FDA to conclude that publication of the Final Sunscreen Rule did not have an effect which warranted warrant inter-agency consultation pursuant to the ESA.

d. Ongoing Rulemaking by FWS and NMFS and Potential Rulemaking from the FDA Highlights the Prematurity and Substantive Issues with Petitioners' Claim

Moreover, given recent rulemaking from the FWS and the NMFS[48] and the indication from the FDA that it intends to issue a proposed rulemaking on sunscreens sometime in the near future,[49] immediate action to restrict oxybenzone and octinoxate is premature. For example, on the agenda of topics to be addressed in a potential rule from the FDA are the active ingredients that FDA considers eligible for use in the monograph. Presumably, this will include a statement on either oxybenzone and/or octinoxate. Additionally, on July 25, 2018 the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) issued a proposed rule, which proposes significant amendments to the regulations governing the Endangered Species Act. As relevant to the immediate Citizen Petition, the proposed rule by FWS and NMFS would amend regulations that implement Section 7 of the Endangered Species Act and clarify the

[47] *National Wildlife Federation*, 414 F.3d at 930.
[48] 50 CFR Part 402, 83 Fed. Reg. 143 page 35178
[49] Unified Agenda of Regulatory and Deregulatory Actions Active Regulatory Actions Listed by Agency: Sunscreen Drug Products for Over-the-Counter Human Use; Tentative Final Monograph, *available* at https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201810&RIN=0910-AF43C

interagency consultation processes. Specifically, in the Proposed Rule, the FWS and NMFS propose to amend the definition of "destruction or adverse modification" found in 50 CFR Part 402.[50] Currently, the definition means:

> "a direct or indirect alteration that appreciably diminishes the value of critical habitat for the conservation of a listed species. Such alterations may include, but are not limited to, those that alter the physical or biological features essential to the conservation of a species or that preclude or significantly delay development of such features."[51]

The proposed definition would add the phrase "as a whole" to the first sentence and remove the second sentence of the current definition**.**[52] Causation would be determined by a "but for" test, under which "[a]n effect or activity is caused by the proposed action if it would not occur but for the proposed action and it is reasonably certain to occur."[53] The "but for" test consists of two separate considerations. Under the first of these two tests, "if an effect or activity would occur regardless of whether the proposed action goes forward, then that effect or activity would not satisfy the "but for" test and would not be considered an effect of the action . . . the second of the two tests speaks to the certainty of whether the effect or activity will occur."[54]

Definitions for "Environmental Baseline" and clarification of jeopardy standards are also proposed in the rule. "Environmental Baseline" would retain its current wording**[55]**, but rather than be part of the "Effects of the Action" definition, "Environmental Baseline" would become a separate definition.**[56]** The FWS and NMFS seek public comment on potential revisions to

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[50] Endangered and Threatened Wildlife and Plants; Revision of Regulations for Interagency Cooperation, 83 Fed. Reg. 35178, 35179 (Jul. 25, 2018) (to be codified at C.F.R. pt. 402).
[51] 50 CFR 402(d) (2018).
[52] Endangered and Threatened Wildlife and Plants; Revision of Regulations for Interagency Cooperation, 83 Fed. Reg. 35178, 35179.
[53] *Id.* at 35183.
[54] *Id.*
[55] 50 C.F.R. §402.02 (d) ("The environmental baseline includes the past and present impacts of all Federal, State, or private actions and other human activities in the action area, the anticipated impacts of all proposed Federal projects in the action area that have already undergone formal or early section 7 consultation, and the impact of State or private actions which are contemporaneous with the consultation in process. Indirect effects are those that are caused by the proposed action and are later in time, but still are reasonably certain to occur. Interrelated actions are those that are part of a larger action and depend on the larger action for their justification. Interdependent actions are those that have no independent utility apart from the action under consideration.")
[56] *Id.* at 35184.

"environmental baseline" as it relates to ongoing federal actions.[57] As the FWS and NMFS note, considerations for ongoing actions are highly complex. Consequently, the FWS and NMFS seek comment on whether the below definition addresses the complexity:

> "Environmental baseline is the state of the world absent the action under review and includes the past, present and ongoing impacts of all past and ongoing Federal, State, or private actions and other human activities in the action area, the anticipated impacts of all proposed Federal projects in the action area that have already undergone formal or early section 7 consultation, and the impact of State or private actions in the action area which are contemporaneous with the consultation in process. Ongoing means impacts or actions that would continue in the absence of the action under review."(emphasis in original).[58]

The proposed rule also emphasizes that a federal action is prohibited by the ESA only if the action causes "appreciable" harm to or appreciably diminishes a listed species or its critical habitat.[59] Within that understanding, is the recognition that "[not every] diminishment, however small, should constitute destruction or adverse modification."[60] This is a key observation, as several recent court cases[61] have ruled that when a species already is jeopardized[62] by degraded baseline conditions, any additional adverse impact is prohibited. The proposed rule rejects this approach, acknowledging that even "for a species with a particularly dire status," who might be appreciably diminished by a smaller impact, "there is no 'baseline jeopardy' status even for the most imperiled species."[63]

The amendments to Section 7 as articulated in the proposed rule would have a significant impact on the ways in which FDA could consult with the NMFS and FWS. Specifically, the

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[57] *Id.*
[58] *Id.*
[59] *See id.*at 35181-82.
[60] Endangered and Threatened Wildlife and Plants; Revision of Regulations for Interagency Cooperation, 83 Fed. Reg. at 35182.
[61] *See id.* at 35182 (discussing *Turtle Island Restoration Network v. United States Dep't of Commerce,* 878 F.3d 725, 735 (9th Cir. 2017); *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 524 F.3d 917, 930 (9th Cir. 2008))).
[62] *See* 50 C.F.R. 402.02 (2018) (defining jeopardize to mean "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species.")).
[63] Endangered and Threatened Wildlife and Plants; Revision of Regulations for Interagency Cooperation, 83 Fed. Reg. at 35182.

amended definitions and the clarification of what constitutes jeopardy bear upon the analysis as it relates to coral and coral reefs. For instance, as highlighted in previous sections here, it is undisputed that there are numerous and well-documented stressors to coral that have nothing to do with sunscreen or sunscreen active ingredients. Taking as true Petitioners' contention that there is some negative impact on coral due to oxybenzone or octinoxate, any such harm is not likely to pass the "but-for causation" standard as articulated in the proposed rule, as there are existing and far more impactful stressors on coral health like rising ocean temperatures, ocean acidification, over-fishing, and agricultural and land use practices, all of which would not be abated by reducing or eliminating the use of oxybenzone and octinoxate as sun filters.

In any event, any potential consultation by FDA under the Endangered Species Act should not occur until FDA has specifically addressed changes to or clarification of the Final Sunscreen Rule and NMFS and FWS have finalized their proposed rule.

3. FDA has complied with its obligations under NEPA

Petitioners finally argue that the FDA has failed to conduct an analysis under the National Environmental Policy Act (NEPA) (42 U.S.C. § 4331 *et seq.).* NEPA is an important articulation of this country's commitment to protecting the environment. NEPA requires that for every major federal action "significantly affecting the quality of the human environment," all agencies of the federal government must include a detailed statement on the "environmental impact of the proposed action," as well as "any adverse environmental effects which cannot be avoided should the proposal be implemented."[64] Like claims brought under the Endangered Species Act, "the standard for 'major federal action' under NEPA and 'agency action' under ESA are much the same."[65]

NEPA requires federal agencies "to the fullest extent possible" to prepare an environmental impact statement ("EIS") in "every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human

[64] 16 U.S.C. § 4332 (2018).
[65] Marbled Murrelet v. Babbitt, 83 F.3d 1068, 1075 (9th Cir.1996).

environment."[66] There are exceptions to the NEPA requirement that agencies prepare an EIS, however, including that an agency need not prepare an EIS "if it finds, on the basis of a shorter 'environmental assessment' (EA), that the proposed action will not have a significant impact on the environment; where an agency lacks discretion concerning the action to be taken; or where the agency action falls under a categorical exclusion."[67]

The provision for categorical exclusions is relevant to this instant Petition. Categorical exclusions are classes of actions that an agency has determined do not "have a significant effect on the human environment."[68] An agency is not subject to the NEPA requirement to "prepare an EIS or even an EA if it finds that its proposed action is subject to a categorical exclusion.[69] Once an agency determines that the action is categorically excluded from NEPA, the "agency's 'decision to classify a proposed action as falling within a particular categorical exclusion will be set aside only if a court determines that the decision was arbitrary and capricious."[70] Where, however, "an agency finds that its proposed action falls within a categorical exclusion the agency must then determine whether there are any 'extraordinary circumstances' that nevertheless require the agency to perform an environmental evaluation."[71]

Over-the-counter drugs (OTC drugs) like sunscreens fall under a categorical exclusion that FDA has deemed do not ordinarily require an analysis under NEPA. Under 21 CFR 25.31, actions related to an OTC monograph, like sunscreens, are categorically excluded from an environmental assessment if the activity does not increase the use of the active moiety; if the action increases the use of the active moiety but the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion; or the substance occurs naturally in the environment when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.[72]

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[66] 42 U.S.C. § 4332(C) (2018).
[67] Safari Club Intern v. Jewell, 960 F. Supp.2d 17 (D.C. Cir. 2013) (citing Monsanto Co. v. Geertson Seed Farms, 561 U.S. 139; Citizens Against Rails–to–Trails v. Surface Transp. Bd., 267 F.3d 1144, 1151 (D.C.Cir.2001); (*Reed v. Salazar*, 744 F.Supp.2d 98, 103 (D.D.C.2010))).
[68] Center for Biological Diversity v. Salazar, 706 F.3d 1085 (9th Cir. 2013)(citing 40 CFR § 1508.4)).
[69] *Safari Club Intern*, 960 F.Supp.2d at 81 (citing *Reed v. Salazar*, 744 F.Supp.2d 98, 103 (D.D.C.2010)).
[70] *Id.* at 81.
[71] *Id.* (citing *Reed*, 744 F. Supp.2d at 116).
[72] *See* 21 CFR 25.31 (2018).

Petitioners criticize the use of a categorical exclusion in this case because they allege that FDA has "fail[ed] to conduct NEPA analysis."[73] This argument is a misunderstanding of the law because categorical exclusions are themselves a direct form of NEPA compliance.[74] Thus, a finding that an ingredient or product is subject to a categorical exclusion is not a dereliction of an obligation under NEPA, but rather is a satisfaction of the obligation.

Moreover, while agencies are expressly permitted to establish categorical exclusions, they must also provide procedures for determining when an environmental assessment or environmental impact statement are nevertheless necessary because of "extraordinary circumstances that indicate the specific proposed action may significantly affect the quality of the human environment."[75] It is precisely because of NEPA's pivotal role and its mandates that the FDA has established procedures and guidance documents to ensure that the agency is in compliance. Indeed, in their Guidance Document, "Guidance for Industry Time and Extent Applications for Nonprescription Drug Products," FDA imposes specific requirements on OTC Drug makers as a direct result of FDA's obligations under NEPA:

> As stated in 21 CFR 25.1, our regulations must be administered in accordance with the policies set forth in the National Environmental Policy Act of 1969 (NEPA). To comply with NEPA, an environmental assessment (EA) of our actions is required unless we determine that a categorical exclusion is warranted (21 CFR 25.20(f) and 25.21). Most actions on OTC drug monographs have been categorically excluded from the EA requirement under 21 CFR 25.31(a), because the actions generally have not increased the use of active ingredients previously marketed in the United States. However, if we determine that an active ingredient not previously marketed in the United States is GRASE and include it in a monograph, this exclusion from the EA requirement would not apply because our action would increase the use of the active ingredient. . .
>
> [t]o help us determine whether the action meets the requirements for exclusion under 21 CFR 25.31(b), you should submit an

[73] Petition to Ban the Active Ingredients Oxybenzone and Octinoxate in Sunscreens and Other Personal Care Products, Center for Biological Diversity, FDA-2018-P-2025 (May 24, 2018).
[74] *See* Center for Biological Diversity v. Salazar, 706 F.3d 1085 (9th Cir. 2013)(stating "Application of a categorical exclusion is not an exemption from NEPA; rather, it is a form of NEPA compliance, albeit one that requires less than where an environmental impact statement or an environmental assessment is necessary.")).
[75] 21 CFR 25.21(2018).

> estimate of the expected introductory concentration of the eligible active ingredient in the aquatic environment (as described in section III of the guidance for industry Environmental Assessment of Human Drug and Biologics Applications 10 1 microgram per liter 15 Contains Nonbinding Recommendations (EA guidance)). If the eligible active ingredient naturally occurs in the environment, we will determine on a case-by-case basis the appropriateness of applying the categorical exclusion under 21 CFR 25.31(c), as described in section III of the EA guidance. If no categorical exclusion applies to a particular FDA action on a monograph, the preparation of an EA is ordinarily required (21 CFR 25.20).[76]

Similarly, FDA has addressed its obligations under NEPA in each of the most recent and relevant sunscreen rules. In the Sunscreen Final Rule, [77] which outlined the active ingredients permitted for use in OTC sunscreen drug products, the FDA concluded that the rulemaking fell under the categorical exclusion in 21 CFR 25.31.[78] Additionally, in a 2011 Final Rule on sunscreen Testing and Labeling, FDA also concluded that the categorical exclusion was applicable.[79] As courts have held, "where a proposed action fits within a categorical exclusion, full NEPA analysis is not required."[80] Contrary to Petitioners' assertion then, FDA has rendered a determination under NEPA—it is just that Petitioners are not in agreement with FDA's determination. As such, Petitioners attempt to convert an analysis under NEPA from a procedural posture to a substantive one. NEPA is not intended to supplant the agency's underlying determination as "NEPA is concerned with process alone and 'merely prohibits uninformed-rather than unwise-agency action.'"[81]

Accordingly, FDA has explicitly determined that a categorical exclusion is appropriate in instances involving OTC monograph products and has therefore satisfied its obligations under NEPA.

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[76] Guidance for Industry Time and Extent Applications for Nonprescription Drug Products, pg 15-16.
[77] 21 CFR Parts 310, 352, 700, and 740.
[78] *See id*. at 27686.
[79] Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use 2011 Rule on Labeling, 76 Fed. Reg. 117 (June 17,2011).
[80] Center for Biological Diversity v. Salazar, 706 F.3d 1085 (9th Cir. 2013) (quoting Wong v. Bush, 542 F.3d 732, 737 (9th Cir. 2008)).
[81] Turtle Island Restoration Network v. U.S. Dep't of Commerce, *et. al*., 878 F.3d 725 (9th Cir. 2017)(quoting Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 348 (1985)).

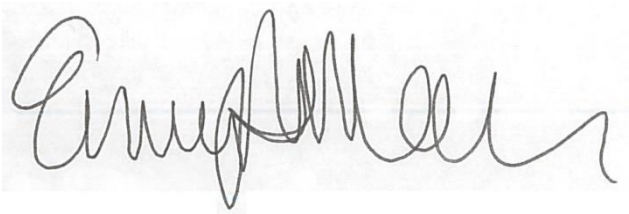
Conclusion

UV-filters such as oxybenzone and octinoxate play a vital role in public health by protecting individuals from the harmful short-term and long-term effects of the sun, which include skin cancer and early aging. A review of the scientific evidence amassed by globally respected and credible scientific organizations and government agencies indicate that (i) the measured concentrations of these filters around the world been extremely variable and generally at barely detectable levels of a few parts per trillion; and (ii) the global coral mass bleaching is primarily caused by rising water temperatures associated with climate change.

Restricting the use of oxybenzone and octinoxate based on a very limited number of reports from which concrete conclusions cannot be drawn would be contrary to the existing scientific weight of evidence and set a precedent for poor policy decisions. No published study has linked exposure to oxybenzone and/or octinoxate to adverse effects on coral reef health in a native setting, or associated oxybenzone and/or octinoxate with a reduced ability of native coral reefs to respond to other environmental stressors. When viewed in its entirety, the currently available scientific evidence on the causes of coral reef degradation around the world overwhelmingly demonstrates that climate change is the primary cause. Additionally, FDA has met its obligations under Section 7 of the ESA with regard to inter-agency consultation prior to engaging in agency action, as defined in Section 7 of the ESA and the absence of such consultation was appropriate in connection with publication of the Final Sunscreen Rule in 1999. Finally, FDA has met its obligation under NEPA by exercising its discretion to claim a categorical exclusion for OTC monograph drugs, and Petitioner presents no evidence to the contrary.

As such, we respectfully request that the FDA deny the requests sought in the "Petition to Ban the Active Ingredients Oxybenzone and Octinoxate in Sunscreens and Personal Care Products." We thank the FDA for the opportunity to provide comments.

Sincerely,



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