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Food and Drug Administration
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CITIZEN PETITION: DOCKET NO. FDA-2021-N-0352

The Personal Care Products Council (PCPC)[1] and the Consumer Healthcare Products Association (CHPA)[2] appreciate the opportunity to comment on the Food and Drug Administration's (FDA or Agency) Notice of Intent to Prepare an Environmental Impact Statement (EIS) to evaluate environmental effects for marketing certain over the counter (OTC) sunscreen products as our members are involved in the manufacture, supply, or are otherwise involved in the development and sale of OTC sunscreen products. The National Environmental Policy Act (NEPA) (42 U.S.C. § 4331 *et seq.)* 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

[1] Founded in 1894, the Personal Care Products Council (PCPC) is the voice and advocate for 600 member companies representing the $450 billion global cosmetics and personal care products industry. PCPC's members represent approximately 90% of the U.S. beauty industry and are some of the most beloved and trusted brands in beauty and personal care today. As manufacturers, distributers and suppliers of a diverse range of products millions of consumers rely on every day – from sunscreens, toothpaste and shampoo to moisturizer, makeup and fragrance – PCPC's member companies are global leaders committed to safety, quality and innovation. For more information on cosmetics and personal care products and their ingredients, please visit www.CosmeticsInfo.org.
[2] The Consumer Healthcare Products Association (CHPA – www.chpa.org), founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices.

action," (Environmental Impact Statement or EIS) as well as "any adverse environmental effects which cannot be avoided should the proposal be implemented."

Of relevance to this recent FDA Notice of Intent, there are circumstances under which an agency may not need to prepare an EIS to satisfy NEPA. 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."[3] Thus, we question why any discussion of FDA performing an EA as, at least, a preliminary step is absent from the instant Notice of Intent. Similarly, we are puzzled by the lack of analysis as to why the relevant categorical exclusion for actions related to an OTC drug monograph is not applicable in this case. We focus our Comments to address these key points.

I. Categorical Exclusion

To begin, we are perplexed that the Notice of Intent lacks analysis as to why the categorical exclusion does not apply here. Categorical exclusions are classes of actions that an agency has determined do not "have a significant effect on the human environment."[4] 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.[5] 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."[6] Where, however, "an agency finds that its proposed action falls within

[3] 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))).
[4] Center for Biological Diversity v. Salazar, 706 F.3d 1085 (9th Cir. 2013)(citing 40 CFR § 1508.4)).
[5] Safari Club Intern, 960 F.Supp.2d at 81 (citing Reed v. Salazar, 744 F.Supp.2d 98, 103 (D.D.C.2010)).
[6] Id. at 81.

a categorical exclusion the agency must then determine whether there are any 'extraordinary circumstances' that nevertheless require the agency to perform an environmental evaluation."[7]

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 (ppb); 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. Existing scientific evidence supports that the estimated concentration of oxybenzone and octinoxate at the point of entry to the aquatic environment will be below 1 ppb. A recent conservative assessment of oxybenzone exposure across the United States in the freshwater environment from down-the-drain emissions determined that the reasonable worst case predicted environmental concentration was 0.15 ppb (90^{th} percentile concentration).[8] While not published, but following the same exposure modeling approach, the reasonable worst case predicted concentration for octinoxate would be lower than oxybenzone. This is because less octinoxate is used in the United States,[9] a greater portion of octinoxate is removed in wastewater treatment,[10] and octinoxate is also readily biodegradable. Octinoxate is considered readily biodegradable, as demonstrated by standard test data (generated following the

[7] Id. (citing Reed, 744 F. Supp.2d at 116).
[8] Burns et al. (2021) National scale down-the-drain environmental risk assessment of oxybenzone in the United States. Integr. Environ. Assess. Manag. DOI: 10.1002/ieam.4430.
[9] Euromonitor (2020) Euromonitor passport. www.euromonitor.com
[10] Liu et al. (2012) Occurrence and removal of benzotriazoles and ultraviolet filters in a municipal wastewater treatment plant. Environ. Pollut. 165, 225 – 232. DOI: 10.1016/j.envpol.2011.10.009

OECD 301B guideline) submitted to the European Chemicals Agency (ECHA) as part of the ingredient's REACH dossier. [11]

For the marine environment, there is monitoring data from Hawaii which suggest that the concentration of oxybenzone and octinoxate do not exceed 1 ppb. The 90th percentile measured concentration of oxybenzone was 0.07 ppb (0.14 ppb maximum), while octinoxate was not quantifiable at any of the sites studied.[12] As octinoxate is readily biodegradable, it is therefore likely that quantifiable environmental concentrations of octinoxate were not detected because the material is biodegraded by microorganisms present in the environment. A recent critical review of UV filter exposure near coral reefs, Mitchelmore et al. (2021),[13] did identify another monitoring study from Hawaii,[14] but determined that the high oxybenzone concentrations reported in the study were clear outliers. The Mitchelmore et al. (2021) review suggested this unrealistic aquatic exposure finding could be due to analytical issues as key quality assurance and control attributes were missing from the study and the performance of the analytical method was poor in comparison to other studies published at the time (e.g., exceedingly high limits of detection and quantification). Mitchelmore et al. (2021) concluded that these data[15] are not suitable to inform on aquatic exposure or environmental risk assessment. For these reasons, we

[11] European Chemicals Agency (ECHA). (2020). Information on chemicals: registration dossier, octinoxate. https://echa.europa.eu/registration-dossier/-/registered-dossier/15876.
[12] Mitchelmore et al. (2019) Occurrence and distribution of UV-filters and other anthropogenic contaminants in coastal surface water, sediment, and coral tissue from Hawaii. Sci. Total. Environ. 670 398 – 410. DOI: 10.1016/j.scitotenv.2019.03.034
[13] Mitchelmore et al. (2021) A critical review of organic ultraviolet filter exposure, hazard, and risk to corals. Environ. Tox. Chem. **40** 967 – 988. DOI: 10.1002/etc.4948.
[14] Downs et al. (2016) 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. Arch. Environ. Con. Tox. **70** 265 – 288. DOI: 10.1007/s00244-015-0227-7.
[15] Downs et al. (2016) 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. Arch. Environ. Con. Tox. **70** 265 – 288. DOI: 10.1007/s00244-015-0227-7.

believe that the categorical exclusion would be appropriately applied here based on the currently available reliable science.

Further, FDA has previously addressed its obligations under NEPA in each of the most recent and relevant sunscreen rulemakings by relying on the categorical exclusion most typically associated with these products. For example, in the 1999 stayed Final Rule, 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.[16] Additionally, in a 2011 Final Rule on sunscreen Testing and Labeling, FDA also concluded that the categorical exclusion was applicable.[17] Critically, FDA also relied on the categorical exclusion for OTC monographs when proposing the sunscreen Tentative Final Monograph in 2019.[18] Specifically, in section XIV, of the 2019 sunscreen Tentative Final Monograph, FDA addressed the Environmental Impact of its proposed rulemaking. There, FDA stated that, "[w]e have determined under 21 CFR 25.31(c) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required."[19]

In this Notice of Intent, FDA does not address the relevance or applicability of the categorical exclusion that is often applied to sunscreen products. Instead, FDA states that it is beginning the public scoping process "because of questions raised about the extent to which two sunscreen active ingredients (oxybenzone and octinoxate) may affect coral and/or coral reefs."

[16] See 21 CFR Parts 310, 352, 700, and 740.
[17] Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use, 76 Fed. Reg. 35620, 35658 Federal Register Volume 76, Issue 117 (June 17, 2011).
[18] Sunscreen Drug Products for Over-the-Counter Human Use, 84 Fed. Reg. 6204, 6251 (February 26, 2019).
[19] Id.

The “questions raised” appear to stem from three groups of activities: public comments received by the FDA on the 2019 proposed Tentative Final Monograph, research activities by the National Oceanic and Atmospheric Administration (NOAA) Coral Reef Conservation Program, and state legislative actions resulting in the restriction of the sale of sunscreens that include the active ingredients oxybenzone or octinoxate. Though the Notice of Intent does not explicitly state that these activities are the “extraordinary circumstances” that would override a relevant categorical exclusion, assuming for argument’s purpose that they are, the lack of analysis on the applicability of the categorical exclusion is concerning.

While public comments received on an agency rulemaking require thoughtful consideration by the relevant federal agency, whether such comments rise to the level of “extraordinary circumstances” in the context of NEPA is less clear. Similarly, that other federal agencies or departments are examining similar or related topics arguably should not compel FDA to decline to apply a relevant categorical exclusion since each agency implements NEPA according to its own regulations and procedures. In the Notice of Intent, FDA referenced ongoing work by NOAA’s Coral Reef Conservation Program; however, PCPC has previously expressed concerns to NOAA over the reliability of the data upon which it cited to make statements about alleged impacts on coral reefs due to specific UV filters.

For instance, a risk assessment is a critical component of determining the likelihood for an ingredient to elicit an adverse effect in the environment. For a risk assessment, two critical elements are needed - the concentration of an ingredient that causes toxicity and the concentration of the ingredient that is present in the environment. It is then possible to evaluate the likelihood of an ingredient causing an adverse environmental effect. To maximize the

evidence used in the assessments, relevant peer-review literature is identified and subsequently evaluated for reliability prior to including it in the risk assessment.

A recent critical review of the exposure, hazard and risks UV filters pose to coral concluded there was limited evidence based on currently available scientific data to suggest that UV filters at their current levels are causing significant harm to corals.[20] Importantly, the review identified significant flaws that undermine the reliability of all the existing UV filter coral toxicity data. While studies have been through the publishing journal's scientific peer-review process, this process is often insufficient to ensure that data and therefore scientific conclusions can be relied upon. The design or execution of a study may be flawed or too poorly documented to reproduce and therefore cannot be used as reliable data or evidence of an effect. For these reasons, when regulatory authorities conduct risk assessments, it is critical that data taken from the peer-reviewed literature must first be evaluated to ensure the data and conclusions of the study are robust and reliable.

The NOAA Coral Reef Conservation Program does not provide published chemical environmental risk assessment guidance; therefore, we recommend following data reliability guidance provided by the NOAA Office of Restoration for the development of their Chemical Aquatic Fate and Effects (CAFE) database, U.S. Environmental Protection Agency Office of Pesticide Programs (USEPA OPP), or appropriate methods published in the peer-reviewed literature (e.g., CRED[21]). Both agencies provide published data reliability guidelines for the use of peer-reviewed studies in regulatory environmental risk assessment activities. The USEPA OPP has a long track record of conducting environmental risk assessments. Their methods are

[20] Mitchelmore et al. (2021) A critical review of organic ultraviolet filter exposure, hazard, and risk to corals. Environ. Tox. Chem. **40** 967 – 988. DOI: 10.1002/etc.4948.
[21] Moermond et al. (2016). CRED: Criteria for reporting and evaluating ecotoxicity data. Environ. Tox. Chem. **35** 1297 – 1309. DOI: 10.1002/etc.3259

well-documented and highly relevant for the environmental risk assessment of UV filters in aquatic environments. USEPA OPP retrieves relevant studies from the ECOTOX database and the peer-reviewed literature in general and conducts a more in-depth reliability assessment. Criteria that an ecotoxicity study must meet in order to be included in agency risk assessments are provided in Attachment 5: Guidelines for invalidation of Open Literature Studies of the "Evaluation Guidelines for Ecological Toxicity Data in the Open Literature".[22] Mitchelmore et al. (2021) highlighted several flaws in all of the coral toxicity data pertaining to UV filters published up to the end of 2020, all of which that would also be identified using these data reliability assessment approaches suggested, in particular the USEPA OPP method or CRED. It has also been determined that the coral toxicity data used to support Hawai'i law S. 2571, Act 104 banning the sale of octinoxate and oxybenzone, is unreliable as it does not meet these USEPA data quality guidelines for environmental risk assessment. A robust environmental risk assessment based on reliable data is critical to facilitate the appropriate course of action for environmental protection.[23,24]

Lastly, FDA references Hawai'i law S. 2571, Act 104, as a factor it considered in issuing this Notice of Intent. While we likely agree with the Agency that the Hawai'i law is significant, that this should form the basis for declining to apply the categorical exclusion is belied by the timing of the law's passage and FDA's own previous rulemaking. As acknowledged by FDA in this Notice of Intent, Hawai'i S. 2571, Act 104, was signed into law on July 3, 2018. The 2019 Tentative Final Monograph for sunscreens was published in the Federal Register on February 26,

[22] USEPA Office of Pesticide Programs (2011) Evaluation guidelines for ecological toxicity data in the open literature. Attachment 5: Guidelines for invalidation of Open Literature Studies Available from: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/evaluation-guidelines-ecological-toxicity-data-open#att_5 (accessed 6/10/2021).
[23] USEPA, 2003. A summary of general assessment factors for evaluating the quality of scientific and technical information. EPA 100/B-03/001, Science Policy Council. Washington DC.
[24] USEPA, 1998. Guidelines for ecological risk assessment. EPA/630/R-95/002F. Washington D.C.

2019, some 238 days *after* the Hawai'i bill was signed into law. Yet, as mentioned previously, in the 2019 Tentative Final Monograph, FDA invoked and relied upon the categorical exclusion for monograph drugs. Notwithstanding that Hawai'i S.2571, Act 104, contained a delayed effective date of January 1, 2021, any potentially relevant extraordinary circumstances arguably occurred in 2018 prior to FDA initiating the 2019 rule. It is therefore confusing that this law is cited by the FDA now, given that the law was passed, and information of its existence was available to the Agency in 2019. Further, the coral toxicity data this law was based upon would not be considered reliable for environmental risk assessment by USEPA and therefore, decision-making.

II. Environmental Impact Analysis vs Environmental Assessment

We also note the unusual posture in that FDA appears to be proceeding directly to an EIS rather than beginning first with an EA. As FDA has recognized, an EA provides sufficient information and analysis for FDA to determine whether to prepare an EIS or issue a finding of no significant impact.[25] Further, an EA requires a complete review of environmental issues associated with the relevant substance(s), any potential mitigation measures, and alternatives.[26] Without conducting an EA first, FDA risks moving on to the EIS without having addressed all relevant considerations. This could create uncertainty regarding the scope of the EIS, notwithstanding FDA's request for comments on the public scoping for the EIS. As FDA has noted in the past, the EA is part of ensuring an efficient environmental review.[27] Even when an EA results in the decision to complete an EIS, the EA is a valuable step. It should therefore be completed in this case prior to moving on to an EIS.

[25] See 21 CFR 25.15(a)-(b).
[26] Guidance for Industry Environmental Assessment of Human Drug and Biologics Applications at 9-12, July 1998.
[27] See 61 FR 14922 (proposed Apr. 3, 1996) (republished May 1, 1996 (61 FR 19476)).

Relatedly, an EA provides the valuable opportunity for public participation throughout the full NEPA process. While this current Notice of Intent invited Comments, it is difficult to understand why FDA would remove an initial feedback opportunity by going directly to the EIS before receiving public input regarding the relevant substances. FDA has noted that "an EA should be 'a document that allows the public to understand the agency's decision' is consistent with the Council on Environmental Quality (CEQ) environmental policies and objectives and will not be deleted. NEPA procedures must ensure that environmental information is available to public officials and citizens."[28] An EA essentially creates a record of the agency's decision making that is critical for public transparency and understanding. By not developing an EA first, FDA has acted such that a public document explaining the Agency's decision to conduct a full EIS will not exist. Thus, FDA has not clearly articulated its basis for deciding that an EIS is necessary (as would usually occur through an EA). We are concerned that this will cause confusion over any purported risks associated with the relevant ingredients.

III. Impact on GRAS Decision

Finally, as FDA prepares to publish any proposed administrative order on sunscreens, we respectfully remind FDA that it does not appear that an EIS mandates any particular action by FDA, either in FDA regulations, CEQ regulations, or NEPA itself, as it relates to FDA's generally recognized as safe (GRAS) decisions. The implementing CEQ regulations provides that "[t]he purpose and function of NEPA is satisfied if Federal agencies have considered relevant environmental information, and the public has been informed regarding the decision-

[28] National Environmental Policy Act; Revision of Policies and Procedures, 62 Fed. Reg. 40570, 47586 (July 29, 1997).

making process. *NEPA does not mandate particular results or substantive outcomes*."[29] FDA regulations provide that they are intended to supplement these implementing CEQ regulations.[30]

In the FDA-specific context, regulations provide that, when an EIS is conducted, FDA must also complete a record of decision (ROD).[31] The ROD must state what the decision was, identify and discuss alternatives considered, state whether all practical means to avoid or minimize the environmental harm have been adopted and, if not, why not, and summarize the program for monitoring and enforcing the practical means adopted.[32] There is no discussion of a mandate that certain decisions be made (or not made) based on the EIS, just that the impact and alternatives be discussed.

We appreciate the opportunity to provide the FDA with comments and we respectfully urge FDA to consider the positions raised herein.

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[29] 40 CFR 1500.1(a) (emphasis added); see also Turtle Island Restoration Network v. United States Department of Commerce, et. al., 878 F.3d 725 (9th Cir. 2017)(quoting Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 348, 109 S.Ct. 1935 (1985) ("NEPA is concerned with process alone and 'merely prohibits uninformed-rather than unwise-agency action.")).
[30] See 21 CFR § 25.1.
[31] See 21 CFR 25.43.
[32] Id.