DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 23, 2020

Tom Neltner
Environmental Defense Fund
1875 Connecticut Ave. N.W.
Washington, DC 20009

Sent via email to: tneltner@edf.org

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to revise its regulations for: color additives at 21 C.F.R. Parts 70 and 71; food additives, GRAS substances, and food contact substances (FCS) at 21 C.F.R. Part 170; and food additive petitions at 21 C.F.R. Part 171 as follows:

1) Add or revise definitions for the following terms to § 70.3 for color additives and § 170.3 for food additives, GRAS substances, and food contact substances.

   a) Substance means a food or food component consisting of one or more ingredients and includes: food additives; substances classified as generally recognized as safe (GRAS); pesticide chemical residues in or on a raw agricultural commodity or processed food; pesticide chemicals; color additives; substances covered by a prior sanction; new animal drugs; and ingredients in, or intended for use in a dietary supplement that may be contained in the diet.

   b) Cumulative effect means a toxic or pharmacological effect of a class of chemically-related substances in the diet based on the timing and duration of exposure determined in accordance with [70.16 or 170.16 as appropriate] or pharmacologically-related substances in the diet based on the timing and duration of exposure determined in accordance with [70.11 or 170.18 as appropriate].

   c) Chemically-related substances mean a group of substances the members of which are similar in molecular structure, or in physical, chemical, or biological properties.

   d) Pharmacologically-related substances mean substances that share scientifically

documented properties of a similar or related pharmacological effect.

e) Pharmacological effect means an effect of a substance based on any one of three attributes:
(1) Mechanism of action based on the pharmacologic action at the receptor, membrane or tissue level; or
(2) Physiological effect at the cellular, organ, system or whole-body level; or
(3) Chemical structure.

f) Diet means:
(1) Food, beverages, and substances contained therein;
(2) Potable water as defined at 1240.3(m); and
(3) Dietary supplements as defined at Section 201 of the act.

2) Add new § 70.16 for color additives and § 170.16 for food additives, GRAS substances, and FCSs regarding the determination of classes of chemically-related substances.[Sec. 70.16 or 170.16 as appropriate] Tolerances for chemically-related substances in the diet.

(a) Substances which are similar in molecular structure, or in physical, chemical, or biological properties are regarded as a class of chemically-related substances.

(b) In the absence of evidence to the contrary, the pharmacological or toxic effect of any member of a class of chemically-related substances is presumed to be applicable to the class as a whole.

(c) In the absence of evidence to the contrary, chemically-related substances will be considered as having additive effects.

3) Revise § 70.11 for color additives and § 170.18 for food additives, GRAS substances, and FCSs regarding the determination of classes of pharmacologically-related substances to refer to substances in the diet instead of food additives.

4) Revise requirements for the content of color additive petitions, threshold of regulation submissions, FCS notifications, GRAS notifications, and food additive petitions submitted pursuant to §§ 71.1, 170.39, 170.101, 170.250, and 171.1 respectively to specifically provide an evaluation of any chemically- or pharmacologically-related substances in the diet that includes the following information:

a) Pharmacological effects of substance;

b) Classes of pharmacologically-related substances for each pharmacological effect pursuant to [70.11 and 170.18 as appropriate];

c) Cumulative effect of each class of pharmacologically-related substances;

d) Classes of chemically-related substances pursuant to [70.16 or 170.16 as appropriate];

e) Cumulative effect of each class of chemically-related substances; and

f) Tolerance or acceptable daily intake for each class.

In Appendix A we provide the exact wording of the requested changes to the regulations. In addition, we request that FDA revise associated guidance, forms, and instructions for petitions, notification and submissions. The changes requested for 21 C.F.R. Parts 170 and 171 apply only to human food.

Your application was received by this office on 09/23/2020 and assigned docket number FDA-2020-P-2003. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2020.09.23 15:37:43 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)