MANUFACTURING CHEMISTS ASSOCIATION

1825 CONNECTICUT AVENUE, N.W. WASHINGTON, D.C. 20009 (202) 483-6126

May 16, 1973

To: FOOD, DRUG, AND COSMETIC CHEMICALS COMMITTEE

Subject: FDA Proposal re Regulation of Prior-Sanctioned Food Ingredients

Members:

Attached is a copy of the notice which appeared in the May 15 FEDERAL REGISTER on the above subject. It says that the new Section 121.2000 General will become effective June 14.

MCA comments on the proposal were sent to you October 11. We endorsed proposed Section 121.2000(b) except for omission of three procedural safeguards:

1. An opportunity to submit additional evidence to support the safety of a prior-sanctioned food ingredient prior to the publication of any proposal to alter its status, when such evidence exists.

2. An opportunity to comment on any proposal to alter the status of a prior-sanctioned food ingredient.

3. An opportunity to request a public hearing on any proposal to alter the status of a prior-sanctioned food ingredient.

The attached notice says that the first is not feasible and that FDA does not have a file of all users of prior-sanctioned ingredients. It is suggested that anyone who has significant safety information on a prior-sanctioned ingredient submit such evidence to FDA now, or as it becomes available, or as affirmation of safety is requested. The notice says further that publication of a proposal to place limitations will, in any event, provide for submission of such information.

With regard to the second and third, the notice says that they are governed by the provisions of the act and the

Administrative Procedure Act, and that the Commissioner is considering a revision of all FDA procedural regulations which will deal with these matters with respect to all regulations under Section 701(a) of the act.

Sincerely yours,

M. M. Hoover, Secretary
Food, Drug, and Cosmetic
Chemicals Committee

MMH:gr

Attachment

Distribution "B"

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 121—FOOD ADDITIVES

Subpart E—Prior-Sanctioned Food Ingredients

A proposal was published in the FEDERAL REGISTER of August 12, 1972 (37 FR 16407) to provide for regulation of prior-sanctioned ingredients by revising the title of subpart E of the food additive regulations and establishing general provisions applicable to prior-sanctioned ingredients.

Four comments were received in response to this proposal. All four comments were primarily concerned with the legality of regulating prior-sanctioned food ingredients and with providing procedural safeguards within the proposed regulation. Specific comments were that the exemption from food additive status of prior-sanctioned ingredients set forth in the Federal Food, Drug, and Cosmetic Act section 201(s)(4) cannot be changed as set forth in the proposal; that absence from listing under subpart E of 21 CFR part 121 cannot affect the prior-sanctioned status of food ingredients; that food packaging materials employing prior-sanctioned ingredients cannot be considered food under section 402(a)(1) of the act; and that procedural safeguards permitting opportunity to submit additional evidence of safety of prior-sanctioned ingredients before a proposal to change its status, and a 60-day comment period and opportunity for public hearing, should be included in the regulation for any proposed or final regulations generated from review of prior-sanctioned ingredients.

Having evaluated the comments and other relevant information, the Commissioner concludes as follows:

1. There is no merit to the argument that prior-sanctioned food ingredients are exempt from safety evaluation under the adulteration provisions of the act. such ingredients are poisonous or deldefinition of "food additive" under section 201(s)(4) of the act but are subject to all the requirements of section 402. Subpart E, as promulgated by this order, will incorporate the Commissioner's determinations with respect to the safety of prior-sanctioned ingredients in accordance with section 402 of the act.

2. Section 701(a) of the act is sufficient legal authority to permit promulgation of regulations determining the safety of prior-sanctioned direct and indirect food ingredients, including a finding that any such ingredients are poisonous or deleterious adulterants of food. Prior-sanctioned ingredients used in food packaging which are in contact with food, and consequently may become an indirect adulterant of food, are not excluded from regulation under section 402 of the act.

3. Expansion of subpart E under part 121 is intended to provide a listing of all known prior-sanctioned food ingredients. Whether a food ingredient is used as a result of a determination that it is GRAS, or pursuant to a food additive regulation, or as a result of a prior sanction, the basis for such use should be a matter of public record. Accordingly, the Food and Drug Administration will publish in this subpart all known prior-sanctioned direct and indirect food ingredients and any subsequent limitations placed upon the use of the ingredient when scientific data justifies such limitations. It is acknowledged that not all known prior-sanctions are presently listed in this subpart. This will be remedied by publication of the prior-sanction status of those ingredients supplied in response to the Food and Drug Administration's request for information on prior sanctions (35 FR 5810) and as requests for affirmation of the safety of prior-sanctioned ingredients are acted upon.

4. The respondents requesting procedural safeguards to permit submission of additional evidence of safety prior to any Food and Drug Administration proposal to place limitations on the use of a prior-sanctioned ingredient, is not feasible. The Food and Drug Administration does not have a file of all users of prior-sanctioned ingredients. It is suggested that anyone who has significant safety information on a prior-sanctioned ingredient submit such evidence to the Food and Drug Administration now, or as it becomes available to them, or as they request affirmation of the safety of the prior-sanctioned ingredients. Publication of a proposal to place limitations on the use of a prior-sanctioned ingredient will, in any event, provide for submission of such information.

The request for other procedural safeguards, including statements that interested persons may comment within 60 days upon publication of any proposal to change the regulatory status of a prior-sanctioned ingredient and adversely affected persons may have a right to request a hearing on any consequent final order, are governed by the provisions of the act and the Administrative Procedure Act. The Commissioner is presently considering a revision of all Food and Drug Administration procedural regulations, which will deal with these matters with respect to all regulations issued under section 701(a) of the act.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat.

1055 and 72 Stat. 1784–88, as amended; 21 U.S.C. 321(s), 348, 371(a)) and under authority delegated to the Commissioner (21 CFR 2.120), subpart E of part 121 is amended as follows:

1. The title of subpart E is revised to read, "Subpart E—Prior-Sanctioned Food Ingredients."

2. Section 121.2001 is redesignated as § 121.2005 and a new § 121.2000 is added to read as follows:

§ 121.2000 General.

(a) An ingredient whose use in food or food packaging is subject to a prior sanction or approval within the meaning of section 201(s)(4) of the act is exempt from classification as a food additive. The Commissioner will publish in this subpart all known prior sanctions. Any interested person may submit to the Commissioner a request for publication of a prior sanction, supported by evidence to show that it falls within section 201(s)(4) of the act.

(b) Based upon scientific data or information that shows that use of a prior-sanctioned food ingredient may be injurious to health, and thus in violation of section 402 of the act, the Commissioner will establish or amend an applicable prior sanction regulation to impose whatever limitations or conditions are necessary for the safe use of the ingredient, or to prohibit use of the ingredient.

Effective date.—This regulation shall become effective June 14, 1973.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055 and 72 Stat. 1784–1788, as amended; 21 U.S.C. 321(s), 348, 371(a).)

Dated May 10, 1973.

SAM D. FINE,
Associate Commissioner for Compliance.

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