

MCA

MANUFACTURING CHEMISTS ASSOCIATION

1872 A CENTURY OF SERVICE 1972

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

October 11, 1972

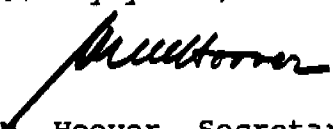
To: FOOD, DRUG, AND COSMETIC CHEMICALS COMMITTEE

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

Gentlemen:

Attached for your information is a copy of the subject
comments.

Sincerely yours,


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

MMH:gr

Attachment

Distribution "B"

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ASI 00002642



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GEORGE E. BEST
VICE PRESIDENT
TECHNICAL DIRECTOR

October 11, 1972

Hearing Clerk
Department of Health, Education,
and Welfare
Room 6-88
5600 Fishers Lane
Rockville, Md. 20852

Dear Sir:

The Manufacturing Chemists Association (MCA) submits the following comments with respect to the Notice of Proposed Rule Making which appeared on pages 16407-8 of the August 12, 1972 FEDERAL REGISTER entitled "Proposal Regarding Regulation of Prior-Sanctioned Food Ingredients".

MCA is a nonprofit trade association of 167 United States company members representing more than 90% of the production capacity of basic industrial chemicals within this country. Many of these companies manufacture prior-sanctioned food ingredients.

Section 121.2000(b) of the regulations reads as follows: "Based upon scientific data or information that shows that use of a prior-sanctioned food ingredient may be injurious to health, and thus is in violation of section 402(a)(1) of the act, the Commissioner will establish or amend the 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".

We endorse this general proposal except for the omission of administrative safeguards. It appears to us that this omission may be at least a partial oversight, since elsewhere in the notice (in proposed section 121.2006 covering talc) there is provision for such a safeguard, namely an opportunity for comment.

ASI 00002643

Hearing Clerk
Department of Health, Education,
and Welfare
October 11, 1972
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We strongly urge that the general section 121.2000 specifically provide for the following three administrative 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.

We note that the first proposed regulation covering a specific prior-sanctioned ingredient (proposed section 121.2006) imposes a requirement that the ingredient, namely talc, be "free" of contamination by asbestos-form particles. Since detection of any contaminant is limited by the sensitivity of available analytical methodology, and it is not possible to prove zero contamination, we urge that the word "free" not be used in this or future similar regulations. Instead we suggest that such regulations speak of the absence of any particular contaminant when tested in accordance with specified methodology.

This opportunity to comment on the proposal is appreciated.

Very truly yours,

George E. Best