



2516 '03 JUL 23 A9:54
July 18, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0434 (Withdrawal of Certain Proposed Rules and other Proposed Actions; Notice of Intent)

Dear Sir or Madam:

The Corn Refiners Association, Inc. (CRA) appreciates the opportunity to comment on the U.S. Food and Drug Administration's (FDA) notice of intent to withdraw the proposed affirmation of GRAS status of unmodified food starches and acid-modified starches as direct and indirect food ingredients (Docket No. 84N-0341).

The CRA is the national trade association representing the corn refining industry of the United States. Members of the Association produce food and industrial starches, sweeteners, ethanol, feed ingredients, vegetable oil, organic acids, amino acids and polyols using the corn wet milling process. A list of our members is attached.

The CRA strongly recommends that the FDA consider completion of the GRAS affirmation for unmodified food starches and acid-modified starches it proposed in the Federal Register of 1985. At that time, the Agency suggested that these products were safe and could be used without limitations other than good manufacturing practices. The Agency received public comments supporting this proposed determination; no comments disagreed with the proposal.

In response to the proposal, the Food Chemicals Codex (FCC) developed detailed specifications for these products which are published in the FCC IV on pages 161 and 158, respectively. These specifications are widely used by industry. Unmodified and acid-modified starches are safely used in hundreds of food products in the United States. Over \$40 million of these products are exported to food industry customers abroad. These customers would also benefit from a final GRAS affirmation of these products.

The proposal to affirm GRAS status was considered for removal in 1991, however, was not removed after consideration of comments. We believe it is in the industry's and FDA's best interest to finalize the proposed GRAS affirmation of unmodified food starches and acid-modified starches. While the Agency discontinued consideration of the vast majority of the items in the 1985 proposal, it concurred with CRA comments and left the starch GRAS proposal on the active list in its 1991 notice.

02N-0434

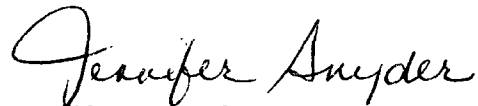
C23

Dockets Management Branch (HFA-305)
Food and Drug Administration
Docket Number 02N-0434
July 18, 2003
Page 2

Nothing about the safety or suitability of these products has changed in the eighteen years since FDA first proposed its GRAS affirmation. No further technical review is necessary to finalize these proposals, and minimal Agency resources would be required to prepare the final administrative documents needed to conclude this proposal. We believe the minor effort needed to finalize these regulations would remove any questions that might be raised in the future concerning the safety and suitability of unmodified food starches and acid-modified starches as food ingredients. We agree with the Agency's conclusion in 1985 that these starches pose no hazard to the public at current or expected use levels.

Thank you for the opportunity to provide FDA with our comments on this important issue to the corn wet milling industry.

Sincerely,



Jennifer W. Snyder
Senior Director
Regulatory and Technical Affairs

Dockets Management Branch (HFA-305)
Food and Drug Administration
Docket Number 02N-0434
July 18, 2003
Page 3

MEMBER COMPANIES
Corn Refiners Association, Inc.
1701 Pennsylvania Avenue, N. W.
Washington, D. C. 20006

Archer Daniels Midland Company
P. O. Box 1470
Decatur, IL 62525

Plants:

Cedar Rapids, Iowa
Decatur, Illinois
Clinton, Iowa
Marshall, Minnesota
Columbus, Nebraska

Cargill, Incorporated
P. O. Box 9300
Minneapolis, Minnesota 55440

Plants:

Blair, Nebraska
Cedar Rapids, Iowa
Eddyville, Iowa
Dayton, Ohio
Memphis, Tennessee
Wahpeton, North Dakota
Hammond, Indiana
Decatur, Alabama
Dimmitt, Texas

Corn Products International, Inc.
5 Westbrook Corporate Center
Westchester, Illinois 60154

Plants:

Argo, Illinois
Stockton, California
Winston-Salem, North Carolina

National Starch and Chemical Company
P. O. Box 6500
Bridgewater, New Jersey 08807

Plants:

Indianapolis, Indiana
North Kansas City, Missouri

Penford Products Co.
(A company of Penford Corporation)
P. O. Box 428
Cedar Rapids, Iowa 52406

Plant:

Cedar Rapids, Iowa

Roquette America, Inc.
1417 Exchange Street
Keokuk, Iowa 52632

Plant:

Keokuk, Iowa

A. E. Staley Manufacturing Company
(A subsidiary of Tate & Lyle, PLC)
P. O. Box 151
Decatur, Illinois 62525

Plants:

Decatur, Illinois
Lafayette, Indiana (2)
Loudon, Tennessee