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December 10, 2003

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

RE: [Docket No. 2003N-0506] Agency Emergency Processing Request Under Office of Management and Budget Review; Experimental Study of Possible Footnotes and Cueing Schemes to Help Consumers Interpret Quantitative *Trans* Fat Disclosure on the Nutrition Facts Panel
68 Federal Register 63801, November 10, 2003

Dear Sir or Madam:

The National Food Processors Association (NFPA) submits the following comments on the docket referenced above.

1350 I Street, NW
Suite 300
Washington, DC 20005
202-639-5900

The National Food Processors Association (NFPA) is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

NFPA has submitted comments several times to FDA on the issue of *trans* fat nutrition labeling and claims, including comments on the issue of the *trans* fat nutrition label footnote proposed in November 2002.

WASHINGTON, DC
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SEATTLE, WA

NFPA opposes OMB approval of the proposed information collection in an FDA experimental study of possible footnotes and cueing schemes to help consumers understand and apply quantitative *trans* fat information displayed on

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the Nutrition Facts panel of a food product label. In addition, NFPA opposes the FDA request for OMB emergency processing of the proposed information collection. Because the experimental study, as designed, fails to consider other approaches to *trans* fat labeling that may be more valid than nutrition label footnotes and other cueing schemes, NFPA believes that there is no need for prompt OMB approval of the proposed consumer research. NFPA believes that FDA must redesign the consumer research project and submit it for OMB approval at a later date. In our view, the consumer research project must be redesigned to ensure that FDA tests all the valid labeling options that consumers might use to interpret correctly and utilize *trans* fat quantitative nutrient declarations. Selecting the correct approach to any additional requirements for *trans* fat labeling will also have an impact on the costs and burdens to the regulated industry in implementing any revised labeling scheme.

With respect to the consumer research being planned by FDA, NFPA notes that it appears the Agency already has concluded that a nutrition label footnote or comparable cueing scheme is the best approach for communicating *trans* fat labeling context to consumers. NFPA questions that assumption. Before proceeding with consumer research to evaluate specific footnote options or cueing schemes, FDA first should study whether nutrition label footnotes or cueing schemes are the most effective means to communicate such information to consumers.

FDA has given no consideration to testing a *trans* fat declaration scheme that is being implemented in Canada; namely, separate quantitative declarations of saturated fat and *trans* fat, and a combined percent Daily Value for saturated fat and *trans* fat. Failure to consider this declaration method both underscores the perception that FDA has decided on a footnote for its approach, and eliminates a viable labeling option from consumer research plans. NFPA encourages FDA to consider the Canadian *trans* fat declaration scheme in its planned consumer research.

Germane to FDA's planned research is the work of the Food and Nutrition Board (FNB) on Dietary Reference Intakes. Within days after the close of the comment period on this notice, it is expected that the FNB report on Use of Dietary Reference Intakes in Nutrition Labeling will be made public. FDA is one of the agencies that commissioned this report from the FNB. While the content of the FNB report is not yet known, the subject of the report directly relates to techniques for presenting contextual information about quantitative nutrition label declarations.

Proper conduct of FDA's planned research on *trans* fat footnotes and other cueing schemes will necessitate consideration of any recommendations in the FNB report. Including any approaches recommended in the FNB report in the planned consumer research design will enhance the quality, utility, and clarity of the information to be collected. Failure to include any approaches recommended in the FNB report in the

design of the consumer research creates the impression that FDA intends not to accept the guidance put forward in the forthcoming FNB report.

Proper performance of FDA's functions resulting from this research project will necessitate serious consideration and consumer testing of all *trans* fat labeling approaches that have any validity, including any options recommended in the FNB report. This consideration will ensure that FDA proposes the *trans* fat labeling option that is best understood by consumers. Without such consideration, the proposed consumer research would be unnecessary and inefficient, and will not have practical utility, since FDA would need to revise its experimental design to accommodate any other valid approaches.

NFPA notes that FDA, in its Supporting Statement for OMB Review of this planned research, states:

> "FDA is trying to finalize its *trans* fat regulations in anticipation of the 2006 effective date for mandatory disclosure of *trans* fat on the NFP [Nutrition Facts panel]. Possible requirements for clarifying footnotes and the form and content of educational initiatives intended to help consumers better understand and use *trans* fat information will necessarily be informed by the findings of the proposed study." (Supporting Statement for OMB Review, Experimental Study of Possible Footnotes and Cueing Schemes to Help Consumers Interpret Quantitative *Trans* Fat Disclosures on the Nutrition Facts Panel (NFP), submitted by Office of Scientific Analysis and Support, Division of Market Studies, Food and Drug Administration, page 7)

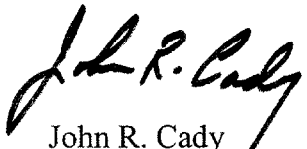
Trans fat nutrition labeling is too important an initiative to be decided with excessive speed, particularly without consideration of all viable options for providing context for quantitative declarations. NFPA believes that FDA must balance its interest for speed in conducting consumer research against the fact that nutrition label changes are already underway to include the *trans* fat quantitative declaration required by the July 2003 final rule (68 FR 41434, July 11, 2003). The prospect of revising labeling requirements while they are being implemented would add costs to the food industry's current relabeling efforts.

As a consequence of these considerations, NFPA opposes the approval of FDA's planned consumer research on *trans* fat nutrition labeling footnotes and cueing schemes, and opposes FDA's request for OMB emergency processing of this research. NFPA does not believe that emergency processing is required or appropriate; indeed, because of the timing of the release of the FNB report, emergency processing is suspect, in our view. NFPA recommends that OMB reject FDA's request, and that FDA re-design its consumer research instrument to accommodate other context-providing *trans* fat

declaration schemes, including any recommendations contained in the forthcoming FNB report.

Thank you for the opportunity to comment on this important issue.

Sincerely,



John R. Cady
President and CEO
National Food Processors Association