CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
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January 24, 2006

Division of Dockets Management (HFA 305)
Food and Drug Administration
5600 Fishers Lane Room 1061
Rockville, MD 20852

Re: Agency Information Collection Activities; Proposed Collection; Comment Request; Notice of a Claim for Generally Recognized as Safe Exemption Based on a Generally Recognized as Safe Determination

The Center for Science in the Public Interest (CSPI)[1] wishes to respond to the Request for Comments on ways to enhance the quality, utility and clarity of information collected in connection with voluntary notifications by companies that have determined that a particular substance is generally recognized as safe (GRAS).

As described in the Dec. 8, 2005 *Federal Register*, the GRAS Notification would "include a detailed summary of the data and information that support the GRAS determination." Such information, along with the Food and Drug Administration's (FDA) response, would be made available in a publicly accessible file. Summaries would not, however, be required to include information inconsistent with a GRAS determination, despite the fact that the notification itself is required to contain "a comprehensive discussion of any reports of investigations or other information that may appear to be inconsistent with the GRAS determination."[2] The most recent *Federal Register* notice states that the "entire GRAS notice" – including negative data – would only be available to the public pursuant to Freedom of Information Act (FOIA) requests.

We believe that the publicly available summary should also include a discussion of any negative or inconsistent data. The summary is the primary means by which interested persons can monitor the intended use of substances that – based on a manufacturer's self-determination – are exempted from regulation as food additives. Unless interested persons are able to view summaries that contain negative as well as positive information about the safety of particular substances, they will have no way of determining whether a GRAS exemption is appropriate.

Although the entire GRAS notification (minus proprietary and other nondisclosable matter) would be publicly available pursuant to a FOIA request, this is not a practical means for

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[1] CSPI is a non-profit consumer advocacy organization that focuses on food safety and nutrition issues. It is supported principally by the 900,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants.

[2] 62 Fed. Reg. 18937 (Apr. 17, 1997). This proposed rule for GRAS notifications is used as guidance by the Agency for the content of GRAS Notifications. http://www.cfsan.fda.gov/~dms/opa-frgr.html.

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interested persons to learn about the safety of a substance before the use of that substance becomes widespread. In recent years, the FDA has experienced significant backlogs in processing FOIA requests. Therefore, it is essential that interested persons be able to view both positive and negative information about a substance in the GRAS Notification summary.

Respectfully submitted,

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