CSPI Center for Science in the Public Interest

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20857

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

Introduction

The Center for Science in the Public Interest (CSPI) is submitting these comments in opposition to the Food and Drug Administration's (FDA) notice that it intends to terminate a number of rulemaking proceedings because they have been pending for more than five years. It is inappropriate to use the length of time a rulemaking is pending as a key determinant in whether a proceeding will be terminated. As the recently issued final rule requiring the labeling of *trans* fatty acids demonstrates, it may take the FDA almost a decade to complete a rulemaking proceeding. A petition to require the addition of *trans* fat to the Nutrition Facts label was filed by CSPI in 1994, a proposal was not issued until five years later, and a final rule was not issued until 2003. Thus, terminating rulemaking proceedings merely because they have been pending for several years is wholly inappropriate.

In particular, we oppose the termination of the following rulemaking proceedings:

- **Caffeine; Deletion of GRAS Status, Proposed Declaration that No Prior Sanction Exists, and Use on an Interim Basis Pending Additional Study**

Caffeine has a wide variety of physiological and behavioral effects. Evidence from human studies suggests that caffeine contributes to adverse reproductive outcomes, including reduced fertility, miscarriage, fetal growth retardation, and reduced-birth-weight babies. In addition, it can adversely affect calcium balance and may contribute to decreased bone density and osteoporosis. The July 2003 *Consumer Reports* published a story disclosing the hidden amounts of caffeine in various foods and discussing the possible health consequences of caffeine on children – nausea, vomiting, diarrhea, cramps, and muscle twitching. Because of the growing concerns about caffeine, CFSAN just this year assigned a "B" priority to conducting "a survey to identify and characterize the sources of caffeine in the food supply." As indicated in the original petition filed by CSPI in 1997, further study is needed on caffeine's health effects. In the interim, FDA should require the quantitative declaration of caffeine content on product labels.

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- **Regulation of Medical Foods**

As we explained in detail in our comments in the proceeding that the FDA commenced on this matter, manufacturers are marketing therapeutic products directly to consumers without prior FDA approval of health claims or FDA review of the suitability of the ingredients for the intended population. In brief, current FDA policies in this area create a loophole for manufacturers to make unauthorized health claims and use ingredients that may not be generally recognized as safe.

The ongoing nature of this problem is illustrated by a consent agreement entered into on June 12, 2003 between the Federal Trade Commission (FTC) and the manufacturer of HeartBar, which is marketed as a medical food. Under the terms of the settlement, HeartBar is prohibited from making claims about a variety of cardiac benefits, such as the reversal of heart damage and the reduction of the need for surgery or heart medications, unless the manufacturer has adequate scientific support. The FDA needs to reexamine its policies in this area and take action against similar products. The proceedings in this area should therefore not be terminated.

- **Food Labeling: Nutrient Content Claims Pertaining to the Available Fat Content of Food**

CSPI believes that misleading claims are being made by producers of products that contain nondigestible fat, including olestra, and that the total amount of fat in a product – regardless of whether it is digestible or nondigestible– should be declared to avoid consumer deception. CSPI has previously filed comments on these matters and urges the FDA to continue work in this area.

- **Food Labeling; Nutrient Content Claims and Health Claims; Special Requirements**

This proposal was designed to ensure the accuracy of health and nutrient content claims by giving FDA the tools it needs to evaluate such claims when: (1) novel ingredients are used; (2) novel or non-standardized testing procedures are used; or (3) records are only available to the person making the claim. In these circumstances, FDA would be given access to the records needed to evaluate the validity of claims. Access to such records is essential to prevent consumer deception and ensure fair competition.

Conclusion

For the foregoing reasons, CSPI believes that the above-referenced proceedings should not be terminated.

Sincerely,

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