

Buchanan Ingersoll on behalf of Merck KGaA dated August 21, 2002.

3. TEA for octyl triazone submitted by Morgan, Lewis & Bockius LLP on behalf of BASF AG dated August 21, 2002.

4. FDA's evaluation and comments on the TEA for amiloxate.

5. FDA's evaluation and comments on the TEA for enzacamene.

6. FDA's evaluation and comments on the TEA for octyl triazone.

Dated: July 5, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0069]

Release of Task Force Report; Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data; Interim Procedures for Health Claims on the Labeling of Conventional Human Food and Human Dietary Supplements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the report of its Task Force on Consumer Health Information for Better Nutrition (the Task force) and two final guidance documents entitled "Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data" and "Guidance for Industry and FDA: Interim Procedures for Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements." These documents further update the agency's approach on how it intends to implement the Court of Appeals decision in *Pearson v. Shalala*. FDA is taking this action to inform interested persons of the release of the Task Force report and to make available the guidances announced in the Task Force report in accordance with FDA's good guidance practices.

DATES: The guidances are final on July 11, 2003. However, you may submit written or electronic comments on the guidances at any time.

ADDRESSES: Submit written requests for single copies of the Task Force report and the final guidances to the Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-800), Food

and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Task Force report and the final guidances.

Submit written comments on the final guidances to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please identify whether you are commenting on one or both of the guidances when you submit your written comments. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT:

Kathleen Ellwood, Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1450.

SUPPLEMENTARY INFORMATION:

I. Background

On December 18, 2002, FDA announced a major new initiative, the Consumer Health Information for Better Nutrition Initiative, to make available more and better information about conventional human food and human dietary supplements to help American consumers improve their health and prevent diseases by making sound dietary decisions. This initiative has as its central focus improving the public availability and consumer understanding of up-to-date scientific evidence on how dietary choices can affect health. FDA announced on January 16, 2003, that one element of this initiative was to set up an FDA Task Force and to issue a report of that Task Force approximately 6 months after the initiative was launched. The Task Force includes representatives from FDA, the Federal Trade Commission (FTC), and the National Institutes of Health.

The Task Force was charged with: (1) Reporting on how the agency can improve consumer understanding of the health consequences of their dietary choices and increase competition by product developers in support of healthier diets, including how the agency should evaluate scientific evidence for qualified health claims in order to achieve these goals; (2) developing a framework of regulations that will give these principles the force and the effect of law; (3) identifying procedures for implementing the initiative, as well as determining the organizational staffing needs necessary for the timely review of qualified health

claim petitions; and (4) developing a consumer studies research agenda designed to identify the most effective ways to present scientifically-based, truthful and nonmisleading information to consumers and to identify the kinds of information known to be misleading to consumers.

On March 13, 2003, the Task Force established a public docket (docket number 2003N-0069) to receive views and comments from interested stakeholders. As part of FDA's continued commitment to ensure that stakeholders remain fully informed of our progress as we implement this initiative, FDA is making available the Task Force report, which includes nine attachments (Attachments A through I). Refer to section II of this document for a brief description of the attachments. The Task Force report entitled "Consumer Health Information for Better Nutrition Initiative—Task Force Report—July 2003" is available on FDA's Web sites at <http://www.fda.gov/oc/mcclellan/chbn.html> or <http://www.fda.gov/ohrms/dockets/default.htm> and by requesting paper copies from the contact person (see **FOR FURTHER INFORMATION CONTACT**). The final guidances are available at <http://www.cfsan.fda.gov/guidance.html> or <http://www.fda.gov/ohrms/dockets/default.htm>.

II. Task Force Report

The Task Force report includes a transmittal memorandum from the Chair and Vice Chair of the Task Force to the Commissioner of Food and Drugs, an executive summary, and the following attachments:

A. Possible Regulatory Frameworks for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements

This attachment describes three options or alternatives for regulating health claims that do not meet the "significant scientific agreement" standard of evidence by which the health claims regulations require FDA to evaluate the scientific validity of claims.

B. Guidance: Interim Evidence-Based Ranking System for Scientific Data

This interim evidence-based ranking system describes a process for systematically evaluating the scientific evidence relevant to a substance/disease relationship that is the subject of a petition for a qualified health claim. The scientific rating system provides a means by which the totality of the publicly available scientific evidence relevant to a substance/disease