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.

[FR Doc. 03–17637 Filed 7–10–03; 8:45 am]

BILLING CODE 4160–01–S

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

relationship can be assigned to one of four ranked levels.

C. Resources for Review of Scientific Data

This attachment describes a process to augment the agency's limited scientific review resources on an as-needed basis by using outside contractors.

D. Consumer Studies Research Agenda—Improving Consumer Understanding and Product Competition on the Health Consequences of Dietary Choices

This attachment sets forth the consumer research studies planned, pending Office of Management and Budget (OMB) approval, to provide the agency with information about consumers' reactions to qualified health claims.

E. Guidance: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements

This attachment describes the interim procedures for qualified health claims in the labeling of conventional human food and human dietary supplements.

F. ''One-Year'' Time Line for Qualified Health Claim Activities

This attachment consolidates the main activities for June 30, 2003, through June 1, 2004.

The Task Force report also contains the list of the Task Force members, a summary of the four stakeholder meetings the Task Force held, and a summary of public comments submitted to the docket on this initiative (see Task Force report attachments G, H, and I, respectively).

III. Final Guidances

A. Background

After the enactment of the Nutrition Labeling and Education Act of 1990 (NLEA), FDA issued regulations establishing general requirements for health claims in food labeling (58 FR 2478, January 6, 1993 (conventional foods); 59 FR 395, January 4, 1994 (dietary supplements)). By regulation, FDA adopted the same procedure and standard for health claims in dietary supplement labeling that Congress had prescribed in the NLEA for health claims in the labeling of conventional foods (see 21 U.S.C. 343(r)(3) and (r)(4)). The procedure requires the evidence supporting a health claim to be presented to FDA for review before the claim may appear in labeling (§ 101.14(d) and (e) (21 CFR 101.14(d) and (e) and 101.70)). The standard requires a finding of ''significant scientific agreement'' (SSA) before FDA may authorize a health claim by regulation (§ 101.14(c)). FDA's current regulations, which mirror the statutory language in 21 U.S.C. 343(r)(3)(B)(i), provide that this standard is met only if FDA determines that there is SSA, among experts qualified by scientific training and experience to evaluate such claims; and that the claim is supported by the totality of publicly available scientific evidence, including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles (§ 101.14(c)). Without a regulation authorizing use of a particular health claim, a food bearing the claim is subject to regulatory action as a misbranded food (see 21 U.S.C. 343(r)(1)(B)), a misbranded drug (see 21 U.S.C. 352(f)(1)), and an unapproved new drug (see 21 U.S.C. 355(a)).

NLEA required that FDA itself initially consider health claims for 10 substance/disease relationships. FDA determined that there was SSA concerning a number of these specified substance/disease relationships and in turn authorized eight claims. Not all relationships that Congress specified to be reviewed were found to meet the standard of SSA, and so not all were authorized by FDA.

Several of the substance/disease relationships for which FDA failed to find significant scientific agreement became the subject of a lawsuit brought by a dietary supplement manufacturer. The case is known as *Pearson* v. *Shalala (Pearson)*. In *Pearson*, the plaintiffs challenged FDA's general health claims regulations for dietary supplements and FDA's decision not to authorize health claims for four specific substance/disease relationships. The district court ruled for FDA (14 F. Supp. 2d 10 (D.D.C. 1998)). However, the U.S. Court of Appeals for the D.C. Circuit reversed the lower court's decision (164 F.3d 650 (D.C. Cir. 1999)).[1] The appeals court held that, on the administrative record compiled in the challenged rulemakings, the first amendment does not permit FDA to reject health claims that the agency determines to be potentially misleading unless the agency also reasonably determines that no disclaimer would eliminate the potential deception.

The court of appeals further stated that it did not ''rule out the possibility that where evidence in support of a claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban it outright.'' (Id. at 659.) Also, the court saw ''no problem with the FDA imposing an outright ban on a claim where evidence in support of the claim is qualitatively weaker than the evidence against the claim.'' (Id. at 659 and n.10.) This language was the genesis of the ''weight-of-the evidence'' criterion discussed in this document.

In the **Federal Register** of October 6, 2000 (65 FR 59855), FDA published a notice announcing its intention to exercise enforcement discretion with regard to certain categories of dietary supplement health claims that do not meet the SSA standard in § 101.14(c). The notice set forth criteria for when the agency would consider exercising enforcement discretion for a qualified health claim in dietary supplement labeling, including as a criterion whether the scientific evidence in support of a given claim outweighed the scientific evidence against it.

As discussed previously, on December 18, 2002, FDA announced the Consumer Health for Better Nutrition Initiative to encourage the flow of high quality, science-based information regarding the health benefits of conventional foods and dietary supplements to consumers. In the **Federal Register** of December 20, 2002 (67 FR 78002), FDA announced that it would apply *Pearson* to health claims in the labeling of conventional foods as well as dietary supplements. The agency also announced the availability of guidance concerning when FDA intended to consider exercising enforcement discretion with respect to health claims that do not meet the standard of SSA. Based on *Pearson*, the December 2002 guidance, like the October 2000 **Federal Register** notice stating FDA's intention to consider exercising enforcement discretion with respect to dietary supplement health claims that do not meet SSA, included as a criterion whether the scientific evidence in support of the claim outweighs the scientific evidence against the claim.

Six days after publication of the December 20, 2002, notice and the guidance, the U.S. District Court for the District of Columbia issued its decision in *Whitaker* v. *Thompson*, 248 F. Supp.2d 1 (*Whitaker*). In *Whitaker*, the district court interpreting *Pearson*, found that ''credible evidence,'' rather than ''weight of the evidence'' is the appropriate standard for FDA to apply in evaluating qualified health claims. In light of *Whitaker*, FDA believes that the weight of the evidence standard in the

[1] On March 1, 1999, the Government filed a petition for rehearsing en banc (reconsideration by the full court of appeals). The U.S. Court of Appeals for the D.C. Circuit denied the petition for rehearsing on April 2, 1999 (172 F.3d 72 (D.C. Cir. 1999)).

October 2000 **Federal Register** notice and the December 2002 guidance must be tempered by the test of credible evidence. Communication of that or any other level of evidence to consumers in a nonmisleading way remains of critical importance.

The reason for the decision to apply *Pearson* to conventional foods is to provide consumers with better health/nutrition information so they can make better dietary choices. By making clear that manufacturers may label foods with truthful and nonmisleading health claims, FDA believes that the guidance will precipitate greater communication in food labeling of the health benefits of consuming particular foods, thereby enhancing the public's health, because consumers will respond to health claims in food labeling by making better informed dietary choices (67 FR 78002).

The decision announced in the December 2002 notice was also based on a desire to avoid further litigation over the constitutionality of the health claims provisions of the NLEA applicable to conventional food labeling to the extent that these provisions do not permit qualified claims. As explained previously, the appeals court held that, on the administrative record compiled in the challenged rulemakings, the first amendment does not permit FDA to reject health claims that the agency determines to be potentially misleading unless the agency also reasonably determines that no disclaimer would eliminate the potential deception. The agency, however, did not have any consumer data to show that a disclaimer would not eliminate the potential deception.

Pearson and subsequent related cases including *Whitaker*, concern dietary supplement labeling, but as stated previously, FDA by regulation adopted the same procedure and standard for health claims for dietary supplement labeling that Congress prescribed in the NLEA for health claims in conventional food labeling. These dietary supplement regulations, like the NLEA provisions in question, do not provide for qualified claims. Hence, based on *Pearson* and related cases, a court faced with a decision by FDA to not permit a qualified health claim for a conventional food might well find the same tension between the NLEA provisions and the first amendment. It is possible that consumer data will show that potentially misleading health claims cannot be cured by disclaimers in at least some cases, but the agency does not have such data for conventional foods, as it did not (and does not) have such data for dietary supplements. Within the next year, the agency will be completing research in this area. The results of this research, together with further evaluation of the regulatory alternatives identified by the Task Force, and evaluation of any additional alternatives, will inform any rulemaking FDA initiates.

In the interim, FDA intends to use the procedures and evidence-based ranking systems for scientific data set out in the below-described guidances on these matters, and consider the exercise of enforcement discretion on a case-by-case basis with respect to qualified health claims in conventional human food and human dietary supplement labeling under certain circumstances. (See *Heckler* v. *Chaney*, 470 U.S. 821 (1985); *Community Nutrition Institute* v. *Young*, 818 F.2d 943, 949–50 (D.C. Cir. 1987)).

FDA believes that its interim approach to qualified claims is a reasonable effort to combine the spirit of the NLEA with the current public health and legal circumstances, and one that reflects practical common sense. And, as the Court of Appeals for the District of Columbia Circuit observed in *Niagara Mohawk Power Corp.* v. *FPC*, 379 F.2d 153, 160, ''Courts are loath to say that good sense is not good law.''

B. Guidance for Industry and FDA: 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 relationship can be assigned to one of four ranked levels. The evidence-based ranking system presupposes that FTC's requirement of ''competent and reliable scientific evidence'' to substantiate an advertising claim related to health or safety has been met. FTC defines ''competent and reliable scientific evidence'' as ''tests, analyses, research, studies, or other evidence'' based upon the expertise of professionals in the relevant area, that has been ''conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted'' in the profession to ''yield accurate and reliable results.'' *In Re: Great Earth International, Inc.*, 110 F.T.C. 188 (1988). In applying the system, FDA intends to consider scientific evidence only if it is competent and reliable. FDA intends to use this interim system, beginning in September 2003, for qualified health claims in the labeling of conventional human food and human dietary supplements. See the **ADDRESSES** section of this notice for information on submitting comments on this final guidance.

C. Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements

FDA intends to use these interim procedures, beginning in September 2003, for qualified health claims in the labeling of conventional human food and human dietary supplements. See the **ADDRESSES** section of this notice for information on submitting comments on this final guidance.

D. The Final Guidances Are Being Issued as Level 1 Guidance under FDA's Good Guidances Practices (GGPs) Regulation (§ 10.115 (21 CFR 10.115))

Consistent with GGPs, the agency will accept comment, but it is implementing these guidance documents immediately in accordance with section 10.115(g)(2) because the agency has determined that prior public participation is not feasible or appropriate. FDA tentatively concludes that the guidances contain no new collection of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidances. Submit a single copy of the electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The Task Force report, two final guidances, and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Interested persons may also access the guidance documents at *http://www.cfsan.fda.gov/guidance.html* or *http://www.fda.gov/ohrms/dockets/default.htm.*

VI. Future Agency Activities

FDA emphasizes that it intends to use the evidence-based ranking system and the procedures on an interim basis. In the near future, the agency intends to publish an advance notice of proposed

rulemaking consistent with the recommendations of the Task Force. As also recommended by the Task Force, FDA intends, within 1 year, to initiate notice-and-comment rulemaking to establish scientific review criteria and procedures for qualified health claim petitions. By that time, FDA expects to complete the consumer studies research as described in the Task Force report (attachment D). The results of this research, together with further evaluation of the regulatory alternatives identified by the Task Force, with the benefit of public comment, and evaluation of any additional alternatives that stakeholders suggest in response to the advance notice of proposed rulemaking, will inform the rulemaking FDA intends to initiate.

Dated: July 8, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–17702 Filed 7–10–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Fiscal Year 2003 Competitive Application Cycle for Operational Health Center Networks (OHCN) CFDA Number 93.224, HRSA–03–105

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the availability of up to $2,100,000 to support costs associated with the operation of a practice management or managed care network or plan, including the purchase or lease of equipment (including the costs of amortizing the principal of, and paying the interest on, loans for equipment).

Authorizing Legislation: Section 330(e)(1)(C) of the Public Health Service Act, as amended authorizes support to health centers that receive assistance under section 330, or at the request of the health centers, directly to a managed care or practice management network or plan that is at least majority controlled and, as applicable, at least majority owned by such health centers receiving assistance under section 330 for the costs associated with the operation of such network or plan, including the purchase or lease of equipment (including the costs of amortizing the principal of, and paying the interest on, loans for equipment). Operational networks are defined as a group of three or more health centers that can demonstrate that an essential, mission-critical function is performed at the network level for the network members, enabling the member centers to perform their business and clinical operations more efficiently and effectively.

DATES: The intended time lines for application submission, review, and award are as follows:

Application Deadline: August 11, 2003.

Grant awards announced: September 30, 2003.

Applications will be considered on time if they are: (1) received by 5 p.m. Eastern Standard Time on August 11, 2003; or (2) postmarked on or before the deadline date given in the **Federal Register** notice and received in time for orderly processing. Applications submitted after the deadline date will be returned to the applicant and not processed. Applicants should obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service or request a legibly dated U.S. Postal Service postmark. Private metered postmarks shall not be accepted as proof of timely mailing. Applications sent to any address other than that specified below are subject to being returned. Applicants should note that HRSA anticipates accepting grant applications online in the last quarter of the fiscal year (July through September). Please refer to the HRSA grants schedule at *http://www.hrsa.gov/grants.htm* for more information.

Where to request and send an application: To obtain a complete application kit, (*i.e.,* application instructions, necessary forms, and application review criteria), contact the HRSA Grants Application Center (GAC) at: HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg, Maryland 20879, Phone: 1–877–HRSA–123 (1–877–477–2123), Fax: 1–877–HRSA–345 (1–877–477–2345), Email: *hrsagac@hrsa.gov.*

When contacting the HRSA GAC please use the following program announcement when requesting application materials: HRSA–03–105, citing ''Operational Health Center Networks.'' Send the original and two copies of the application to the HRSA GAC. Applicants will receive a letter acknowledging the receipt of their application.

Eligible applicants: The following entities are eligible to apply for funding under this announcement:

1. A health center, as defined and funded under section 330 of the Public Health Service Act, acting on behalf of the member health centers and the network.

(A) A health center applying on behalf of a managed care network or plan must have received Federal grants under subsection (e)(1)(A) of section 330 for at least the two consecutive preceding years.

(B) A health center (Community Health Center, Migrant Health Center, Health Care for the Homeless, Public Housing Primary Care and Healthy Schools, Healthy Communities) applying on behalf of a practice management network must have received Federal grants under section 330 for at least the two consecutive preceding years.

2. Operational networks, controlled by and acting on behalf of the health center(s) as defined and funded under section 330 of the Public Health Service Act. At the request of all the member health centers, a network may apply for direct funds if it is at least majority controlled and, as applicable, at least majority owned, by such health centers.

3. Eligibility is limited to public and non-profit organizations, including faith-based and community organizations.

Matching or cost sharing requirement: Grantees must provide at least 60 percent of the total approved cost of the project. The total approved cost of the project is the sum of the HRSA share and the non-Federal share. Applicants must demonstrate that at least 30 percent of the cost sharing requirement is met through cash contributions. The remaining non-Federal share may be met by cash or in-kind contributions.

Application review and funding criteria: Each application submitted by the deadline will be reviewed initially for completeness and eligibility. Applications that are determined to be ineligible, incomplete, or non-responsive will be returned to the applicant without further consideration. Those applications that are determined to be eligible and responsive to the requirements will be reviewed by a panel of reviewers comprised of non-Federal experts using the following objective review criteria:

1. Appropriateness in meeting expectations of the Integrated Shared Development Initiative—extent to which the application effectively demonstrates the integration and coordination of primary care across business and clinical functions of network members.

2. Appropriateness to State Environment and Marketplace—extent to which the application demonstrates both the (a) appropriateness of the network to the State marketplace and/or