These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 (on INDs) have been approved under OMB control number 0910–0014; and those in 21 CFR part 812 (on IDEs) have been approved under OMB control number 0910–0078.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of 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 the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm, http://www.fda.gov/cdrh/guidance.html*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: June 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–13162 Filed 7–6–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0125]

Draft Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims.'' This draft guidance updates the agency's approach to the review of the publicly available scientific evidence for significant scientific agreement (SSA) and qualified health claims. FDA is taking this action to inform interested persons of the system it intends to use to review the scientific evidence in the evaluation of SSA and qualified health claims.

DATES: Submit written or electronic comments on the draft guidance document by September 7, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Nutritional Products, Labeling and Dietary Supplements (HFS–800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD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 the office in processing your request, or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www/fda/gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Paula Trumbo, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 310–436–2579.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims.'' The Nutrition Labeling and Education Act of 1990 (NLEA) was designed to give consumers more scientifically valid information about foods they eat. Among other provisions, NLEA directed FDA to issue regulations providing for the use of statements that describe the relationship between a substance and a disease (''health claims'') in the labeling of foods, including dietary supplements, after such statements have been reviewed and authorized by FDA. For these health claims, that is, statements about substance/disease relationships, FDA has defined the term ''substance'' by regulation as a specific food or food component (§ 101.14(a)(2) (21 CFR 101.14(a)(2)). An authorized health claim may be used on both conventional foods and dietary supplements, assuming that the substance in the product and the product itself meet the appropriate standards in the authorizing regulation. Health claims are directed to the general population or designated subgroups (e.g., the elderly) and are intended to assist the consumer in maintaining healthful dietary practices.

In evaluating a petition for an SSA health claim submitted under § 101.70 (21 CFR 101.70), FDA considers whether the evidence supporting the relationship that is the subject of the claim meets the SSA standard. This standard derives from section 403(r)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(3)(B)(i)), which provides that FDA shall authorize a health claim to be used on conventional foods if the agency ''determines, based on the totality of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.'' This scientific standard was prescribed by statute for conventional food health claims; by regulation, FDA adopted the same standard for dietary supplements health claims (see § 101.14(c)).

The genesis of qualified health claims was the court of appeals decision in *Pearson* v. *Shalala* (*Pearson*). In that case, the plaintiffs challenged FDA's decision not to authorize health claims for four specific substance/disease relationships for dietary supplements. Although the district court ruled for FDA (14 F. Supp. 2d 10 (D.D.C. 1998)), the U.S. Court of Appeals for the DC Circuit reversed the lower court's decision (164 F.3d 650 (DC Cir. 1999)). The appeals court held that 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 a disclaimer would not eliminate the potential deception. The appeals court also held that the Administrative Procedure Act required FDA to clarify the SSA standard for authorizing health claims.

On December 22, 1999, FDA announced the issuance of a guidance entitled ''Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements'' (64 FR 71794). This guidance document was issued to clarify FDA's interpretation of the SSA standard in response to the court of appeals second holding in *Pearson*.

On December 20, 2002, the agency announced its intention to extend *Pearson* to health claims for conventional foods (67 FR 78002). Recognizing the need for an approach for scientific evaluations for qualified health claims, the task force on ''Consumer Health Information for Better Nutrition'' was formed. As part of the task force's final report,[1] FDA developed an interim evidence-based review system that the agency intended to use to evaluate the substance/disease relationships that are subjects of qualified health claims.

In reviewing both the December 22, 1999, guidance document and the 2003 task force report, it became apparent to the agency that the components of the scientific review process for an SSA health claim and qualified health claim are very similar. Because of the similarity between the scientific reviews for SSA and qualified health claims, FDA intends to generally use the approach set out in this draft guidance for evaluating the scientific evidence in petitions that are submitted for an SSA health claim or qualified health claim.

The primary purpose of this document is to set out FDA's current thinking on the process for evaluating the scientific evidence for a health claim, the meaning of the SSA standard in section 403(r)(3) of the act and § 101.14(c), and credible scientific evidence to support a qualified health claim.

This draft guidance is being issued consistent with FDA's good guidance practice regulations (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the scientific review process for SSA and qualified health claims. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in §§ 101.14 and 101.70 have been approved under OMB control number 0910–0381.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance document. Submit a single copy of 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 draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.cfsan.fda.gov/guidance.html*.

Dated: June 28, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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[1]See guidance entitled ''Interim Evidence-based Ranking System for Scientific Data,'' July 10, 2003 (*http://www.cfsan.fda.gov/~dms/hclmgui4.html*).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimated burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Office of Health Information Technology, Health Center Controlled Networks Progress Reports—New

The Office of Health Information Technology (OHIT), Division of State and Community Assistance (DSCA) plans to collect network outcome measures, conduct evaluation of those measures, and create an electronic reporting system for the following new 2007 grant opportunities: Health Information Technology Planning Grants, Electronic Health Record Implementation Health Center Controlled Networks, Health Information Technology Innovations for Health Center Controlled Networks, and High Impact Electronic Health Records Implementation for Health Center Controlled Networks and Large Multi Site Health Centers.

In order to help carry out its mission, DSCA has created a set of performance measures that grantees will use to evaluate the effectiveness of their service programs and monitor their progress through the use of performance reporting data.

OHIT will develop an electronic performance measurement reporting instrument with HRSA's Office of Information Technology. The instrument will be developed to accomplish the following goals: To monitor improved access to needed services, to evaluate the productivity and efficiency of the networks, and to monitor patient outcome measures. Grantees will submit their Progress Reports in a mid-year report and an accumulative annual progress report each fiscal year of the grant.

The estimates of burden are as follows: