DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–5424]

Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements.'' The guidance is based on the report of an FDA Food Advisory Committee (FAC) Working Group that was asked to advise the agency on interpretation of the scientific standard ''significant scientific agreement,'' which FDA applies in its review of scientific data for health claims. This action is being taken to provide guidance to industry and to comply with a recent court decision that instructed FDA to clarify the meaning of the significant scientific agreement standard.

DATES: Written comments should be submitted by February 22, 2000, to ensure adequate consideration in the preparation of a revised guidance, if warranted. However, written comments may be submitted at anytime.

ADDRESSES: Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document. Submit written requests for single copies of the guidance entitled ''Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements'' to the Office of Special Nutritionals (HFS–450), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Send one self-addressed adhesive label to assist that office in processing your request, or include a fax number to which the guidance may be sent. Alternatively, you may request a copy of the guidance by calling 202–205–4168, or you may fax your request to 202–205–5295. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Sharon A. Ross, Center for Food Safety and Applied Nutrition (HFS–450), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4168.

I. Background

SUPPLEMENTARY INFORMATION: The Nutrition Labeling and Education Act of 1990 (NLEA), which amended the Federal Food, Drug, and Cosmetic Act (the act), authorized FDA to allow food labels to carry statements that describe the relationship between a food substance and a disease or health-related condition (''health claims'') (section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B))). To ensure the scientific validity of health claims, NLEA required that FDA authorize a health claim in the labeling of conventional foods only if the agency ''determines, based on the totality of 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'' (section 403(r)(3)(B)(i) of the act (21 U.S.C. 343(r)(3)(B)(i))). By regulation, FDA adopted the same standard for health claims in the labeling of dietary supplements (§ 101.14(c)(21 CFR 101.14(c)).

In 1996, FDA asked its FAC to convene a working group to develop a guide for preparing petitions for health claims. In response to the recent decision of the Court of Appeals for the District of Columbia Circuit in *Pearson* v. *Shalala*, 164 F.3d 650 (D.C. Cir. 1999), which required FDA to clarify the meaning of ''significant scientific agreement,'' the focus of the FAC Working Group shifted to the scientific review of data for health claims and the interpretation of the significant scientific agreement standard. The working group's final report entitled ''Interpretation of Significant Scientific Agreement in the Review of Health Claims'' was made public during the FAC meeting of June 24 and 25, 1999. FDA concurs with the conclusions of the working group and is issuing a guidance based on the working group's final report.

This guidance represents the agency's current thinking on the meaning of the significant scientific agreement standard in section 403(r)(3) of the act (21 U.S.C. 343(r)(3)) and § 101.14(c). 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 statute, regulations, or both.

This guidance is a Level 1 guidance under FDA's good guidance practices (GGP's) (62 FR 8961, February 27, 1997). Consistent with GGP's, the agency is soliciting public comment, but is implementing the guidance immediately to promptly comply with the decision in *Pearson* v. *Shalala*.

II. Comments

Interested persons should submit written comments on the guidance to the Dockets Management Branch (address above), by February 22, 2000, to ensure adequate consideration in the preparation of a revised guidance, if warranted. However, written comments may be submitted at anytime. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of the guidance also is available on the Internet at http://www.cfsan.fda.gov/~dms/guidance.html#lab.

Dated: December 17, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4959]

Draft Guidance for Industry on Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research, Beginning on January 1, 2000; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related

to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research, Beginning on January 1, 2000.'' This document is intended to provide guidance to sponsors of applications that are the subject of an open advisory committee meeting convened by the Center for Drug Evaluation and Research (CDER), beginning January 1, 2000. The draft guidance describes procedures that will be adopted by CDER for making information provided to advisory committee members in connection with such meetings publicly available. The draft guidance also describes how a sponsor should prepare its submission to an advisory committee.

DATES: Submit written comments on the draft guidance document by February 22, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your request. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400.

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

FDA is announcing the availability of a draft guidance for industry entitled ''Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research, Beginning on January 1, 2000.'' This draft guidance is intended to provide guidance to sponsors of applications that are the subject of an open advisory committee meeting convened by CDER, beginning January 1, 2000. The draft guidance describes procedures that will be adopted by CDER for making information that is provided to advisory committee members in connection with such meetings publicly available. The draft guidance also describes how a sponsor should prepare its submission to an advisory committee.

In the **Federal Register** of November 30, 1999 (64 FR 66920), FDA announced the availability of a guidance document entitled ''Disclosure of Materials Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000'' (the disclosure policy guidance). The disclosure policy guidance provided guidance on how FDA interprets the Federal Advisory Committee Act (the FACA) (5 U.S.C. app. 2) and § 314.430 (21 CFR 314.430) with respect to the disclosure of materials provided to advisory committees and how FDA will exercise its discretion under § 314.430(d)(1) in connection with open advisory committee meetings convened by CDER beginning on January 1, 2000. In the disclosure policy guidance, FDA stated that the agency construes the FACA to require that, with respect to any open advisory committee meeting convened pursuant to the FACA, whenever practicable and subject to any applicable exemptions of the Freedom of Information Act (the FOIA) (5 U.S.C. 552), those materials that are provided to the members of an advisory committee in connection with that meeting must be made available for public inspection and copying before or at the time of the advisory committee meeting. The agency also stated in the disclosure policy guidance that FDA interprets § 314.430 to be consistent with the FACA and therefore will exercise its discretion under § 314.430(d)(1) in a manner consistent with the FACA and the FOIA as described in the previous sentence to make available for public inspection and copying materials provided to the members of an advisory committee in connection with open advisory committee meetings convened by CDER, beginning on January 1, 2000. In the disclosure policy guidance, FDA stated its intention to provide further guidance on what sponsors may expect concerning the disclosure of this information.

The draft guidance entitled ''Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research, Beginning on January 1, 2000,'' that FDA is making available today, is intended to provide the procedural information referenced in the disclosure policy guidance. The procedures in this guidance are intended to make the process of complying with the disclosure requirements of the FACA as efficient as possible. The procedures address: (1) The content and organization of a sponsor submission for an advisory committee; (2) the timing of the sponsor submission to CDER; (3) the process by which CDER will review and redact the sponsor submission and the related CDER submission; and (4) the effect this process may have on the time allotted to a review cycle in which an advisory committee meeting occurs.

This draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on the implementation by CDER of the disclosure provisions of the FACA. 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.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

II. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

With respect to the following collection of information, FDA invites comment on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Draft Guidance for Industry on Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research, Beginning on January 1, 2000.

Description: FDA is issuing a draft guidance on procedures that will be adopted by CDER for making information that is provided to advisory committee members in connection with open advisory committee meetings publicly available. The procedures address: (1) The content and organization of a sponsor submission for an advisory committee; (2) the timing of the sponsor submission to CDER; (3) the process by which CDER will review and redact the sponsor submission and the related CDER submission; and (4) the effect this process may have on the time allotted to a review cycle in which an advisory committee meeting occurs. Under existing regulations in 21 CFR 14.35(a), sponsors routinely submit information to the agency that will be provided to advisory committee members in connection with advisory committee meetings. A sponsor may submit a package that the sponsor states should be fully disclosed to the public or a package that contains information the sponsor asserts should be withheld from public disclosure under the FOIA. This draft guidance describes the submission of information to the agency that will be provided to the members of an advisory committee in connection with an open advisory committee meeting related to the testing or approval of a new drug and convened by CDER, beginning on January 1, 2000.

FDA construes the FACA to require that, with respect to any open advisory committee meeting convened pursuant to the FACA, whenever practicable and subject to any applicable exemptions of the FOIA, those materials that are provided to the members of a CDER advisory committee in connection with that meeting must be made available for public inspection and copying before or at the time of the advisory committee meeting. Therefore, under the draft guidance, a sponsor may submit two types of packages of materials for an advisory committee in connection with an open advisory committee meeting convened by CDER: (1) A package that the sponsor states should be fully disclosed to the public because it does not contain information that should be withheld from public disclosure under an exemption under the FOIA; and (2) a package that contains information the sponsor asserts should be withheld from public disclosure under the FOIA and that, therefore, must be reviewed by the agency's Freedom of Information staff to ensure that the appropriate information is redacted. The procedures for submitting the two collections of information are described in the draft guidance.

A. Fully Releasable Submissions

In the guidance, sponsors are strongly encouraged to submit advisory committee packages that may be publicly disclosed in their entirety (i.e., that do not contain any information that the sponsor wishes to assert is exempt from disclosure under the FOIA because it is trade secret or confidential commercial information, or because it is information whose disclosure would constitute an unwarranted invasion of personal privacy, for example, by clearly identifying individual subjects). Sponsors are also encouraged to submit an electronic version of the package.

B. Submissions That Contain Material the Sponsor Asserts is Exempt From Disclosure

A sponsor may believe that it is necessary to include material in an advisory committee package that it believes is exempt from disclosure. As described in the guidance, the agency recommends in this circumstance that the sponsor segregate the material it believes is exempt from disclosure from the disclosable material, clearly designate the material that the sponsor believes is exempt from disclosure, and provide a detailed justification of both why that specific information is necessary for the advisory committee's consideration and why it is exempt from disclosure. Sponsors are also encouraged to submit an electronic version of the package.

1. Description of Respondents

A sponsor of an unapproved new drug application (NDA), NDA supplement, abbreviated new drug application (ANDA), biological license application (BLA), or premarket approval application for a device (PMA) that is the subject of an open advisory committee convened by CDER, beginning January 1, 2000, to the extent permitted under applicable law and unless the unapproved BLA or PMA is being discussed at a segregable portion of a CDER advisory committee meeting (for example, during the afternoon session) and not in conjunction with an NDA, NDA supplement, or ANDA.

2. Burden Estimate

Table 1 of this document provides an estimate of the annual reporting burden for the submission under the guidance of information to CDER that will be provided to the members of an advisory committee in connection with an open advisory committee meeting related to the testing or approval of a new drug and convened by CDER, beginning on January 1, 2000.

a. *Fully releasable submissions*. In calendar year 1998, 30 different sponsors (respondents) submitted background information for open advisory committee meetings regarding the testing or approval of new drugs. CDER expects that annually, approximately the same total number of respondents (i.e., 30 respondents) will submit information for similar open advisory committee meetings. The procedures for submitting this information that are set forth in the draft guidance document were not in place in calendar year 1998. However, based on CDER's experience with the advisory committee process, and given that the guidance document strongly encourages respondents to submit advisory committee packages that may be publicly disclosed in their entirety, CDER estimates that approximately two-thirds of the total number of respondents (i.e., 20 respondents) will submit packages that may be disclosed in their entirety. In calendar year 1998, CDER received a total of 38 submissions from sponsors in connection with open advisory committee meetings. The agency expects that this number will remain the same. However, based on CDER's experience with the advisory committee process and given that the guidance document strongly encourages respondents to submit advisory committee packages that may be publicly disclosed in their entirety, CDER estimates that approximately two-thirds of the submissions it receives (i.e., 25 responses) will be fully releasable, averaging 1.25 responses per respondent. Therefore, FDA estimates that the total annual responses (i.e., the

total number of fully releasable sponsor submissions that will be provided to advisory committees) will be 25. The hours per response is the estimated number of hours that a respondent would spend under the guidance preparing a fully releasable submission in connection with an open advisory committee meeting, including submitting an electronic version of the package. Based on FDA experience and information provided to the agency by the Pharmaceutical Research and Manufacturing Association (PhRMA), FDA estimates that approximately 700 hours on average would be needed per response. Therefore, FDA estimates that 17,500 hours will be spent per year under the guidance by respondents submitting fully releasable information in connection with open advisory committee meetings.

b. *Submissions that contain material the sponsor asserts is exempt from disclosure*. In calendar year 1998, 30 different sponsors (respondents) submitted background information for open advisory committee meetings regarding the testing or approval of new drugs. CDER expects that annually, approximately the same total number of respondents (i.e., 30 respondents) will submit information for similar open advisory committee meetings. The procedures for submitting this information that are set forth in the draft guidance document were not in place in calendar year 1998. However, based on CDER's experience with the advisory committee process, and given that the guidance document strongly encourages respondents to submit advisory committee packages that may be publicly disclosed in their entirety, CDER estimates that approximately one-third of the total number of respondents (i.e., 10 respondents) will submit packages that contain material that the sponsor asserts is exempt from disclosure. In calendar year 1998, CDER received a total of 38 submissions from sponsors in connection with open advisory committee meetings. The agency expects that this number will remain the same. However, based on CDER's experience with the advisory committee process, and given that the guidance document strongly encourages respondents to submit advisory committee packages that may be publicly disclosed in their entirety, CDER estimates that approximately one-third of the submissions it receives (i.e., 13 responses) will contain information that the sponsor asserts is exempt from disclosure, averaging 1.3 responses per respondent. Therefore, the total annual response (i.e., the total number of sponsor submissions that will be provided to advisory committees and that the sponsors assert is exempt from disclosure) is estimated to be 1.3. The hours per response is the estimated number of hours under the guidance that a respondent would spend preparing a submission that contains information that the respondent asserts is exempt from disclosure, including the time FDA expects it will take a sponsor to submit an electronic version of the package and to work with the agency to redact any information that is appropriately exempt from disclosure under the FOIA. Based on FDA experience and information provided to the agency by PhRMA, FDA estimates that approximately 1,400 hours on average would be needed per response. Therefore, FDA estimates that under the guidance, 18,200 hours will be spent per year in connection with open advisory committee meetings by respondents submitting packages that contain information that the respondents assert is exempt from disclosure. The total estimated burden hours under the draft guidance are 35,700.

FDA invites comments on this analysis of information collection burdens.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Submissions	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Fully releasable submissions	20	1.25	25	700	17,500
Submissions that contain material that is claimed to be exempt from disclosure	10	1.3	13	1,400	18,200
Total	30		38		35,700

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

In compliance with section 3507(d) of the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this draft guidance to OMB for review. Interested persons are requested to send comments on this information collection by February 22, 2000, to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

Dated: December 15, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–0588]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a currently Approved collection; *Title of Information Collection:* Authorization agreement for electronic forms transfer; *Form No.:* HCFA–0588 (OMB# 0938–0626); *Use:* The information is needed