Information.'' This guidance provides: (1) A framework for making regulatory decisions on drug substance sameness in terms of polymorphic form and (2) decision trees which provide a recommended course to monitor and control polymorphs in the drug substance and/or drug product when the drug substance exists in relevant polymorphic forms.

On December 20, 2004 (69 FR 75987), the FDA announced the availability of the draft version of this guidance. The public comment period closed on March 21, 2005. A number of comments were received, which the agency considered carefully as it finalized the guidance and made appropriate changes. Most of the changes to the guidance were made to clarify statements in the draft guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on pharmaceutical solid polymorphism. 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. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: June 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–13171 Filed 7–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0249]

Draft Guidance for Industry: Preparation of Investigational Device Exemptions and Investigational New Drug Applications for Products Intended to Repair or Replace Knee Cartilage; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Cartilage'' dated July 2007. The draft guidance provides to sponsors recommendations about certain information that should be included in an investigational device exemption (IDE) or investigational new drug application (IND) for a product intended to repair or replace knee cartilage. The draft guidance, when finalized, will supplement other FDA publications on IDEs and INDs.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by October 9, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448; or the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800; or by calling CDRH at 240–276–3150 or by faxing a request to CDRH at 240–276–3151. To receive an electronic copy, send an e-mail request to *dsmica@fda.hhs.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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:

Brenda R. Friend, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210; or

Aric D. Kaiser, Center for Devices and Radiological Health (HFZ–410), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3676.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Cartilage'' dated July 2007. The draft guidance document provides to sponsors recommendations about certain information that should be included in an IDE or IND for a product intended to repair or replace knee cartilage. For the purposes of the draft guidance, a product intended to repair or replace knee cartilage, as with other articular cartilage repair or replacement products, may include a biologic, device, or combination product whose components would be individually regulated by CDRH and CBER.

FDA prepared this draft guidance to address issues that may arise in the development of articular cartilage repair or replacement products. The draft guidance also reflects input received from the public and the Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC) at the March 3 to 4, 2005, CTGTAC meeting. The draft guidance, when finalized, will supplement other FDA publications on IDEs and INDs.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. 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 requirement 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 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]

BILLING CODE 4160–01–S

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*.