Section Head, Health Services Research and Rural Health Policy, University of Nebraska; Lee Partridge, Senior Health Policy Advisor, National Partnership for Women and Families; Rebecca Snead, Executive Vice President/Chief Executive Officer, National Alliance of State Pharmacy Associations; William A. Steel, President, The National Grange; Marvin Tuttle, Jr., CAE, Executive Director and Chief Executive Officer, Financial Planning Association; Catherine Valenti, Chairperson and Chief Executive Officer, Caring Voice Coalition; and Grant Wedner, Vice President, Partnerships and Corporate Development, Daily Strength, Inc.

The agenda for the December 4, 2007 meeting will include the following:

- Recap of the previous (September 20, 2007) meeting.
- Medicare Enrollment, Outreach, Education, and Partnering Activities Update.
- Public Comment.
- Listening Session with CMS Leadership.
- Next Steps.

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to Lynne Johnson at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Individuals not wishing to make a presentation may submit written comments to Ms. Johnson at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

Individuals requiring sign language interpretation or other special accommodations should contact Ms. Johnson at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

Authority: Sec. 222 of the Public Health Service Act (42 U.S.C. 217a) and sec. 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR 102–3).

(Catalog of Federal Domestic Assistance Program No. 93.733, Medicare—Hospital Insurance Program; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 19, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–21080 Filed 10–25–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0205]

Exocrine Pancreatic Insufficiency Drug Products; Extension to Obtain Marketing Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it intends to continue to exercise enforcement discretion to ensure the continued availability of exocrine pancreatic insufficiency drug products after April 28, 2008. FDA intends to exercise its enforcement discretion with respect to unapproved pancreatic enzyme drug products until April 28, 2010, if the manufacturers have investigational new drug applications (INDs) on active status on or before April 28, 2008, and have submitted new drug applications (NDAs) on or before April 28, 2009. FDA is granting this extension to ensure the availability of exocrine pancreatic insufficiency drug products during the additional time needed by manufacturers to obtain marketing approval.

DATES: The period during which FDA intends to exercise its enforcement discretion against unapproved pancreatic insufficiency drug products is extended to April 28, 2010, if the manufacturer has an active IND on or before April 28, 2008, and has submitted an NDA on or before April 28, 2009.

FOR FURTHER INFORMATION CONTACT: Mary Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 28, 2004 (69 FR 23410) (the 2004 notice), FDA announced that all exocrine pancreatic insufficiency drug products are new drugs and announced the conditions for continued marketing of the drug products. The 2004 notice covered pancreatic enzyme preparations containing the ingredients pancreatin and pancrelipase. Both ingredients are extracted mainly from hog pancreas and contain principally the enzymes amylase, protease, and lipase. Pancreatic extract drug products are indicated as replacement therapy to treat conditions associated with exocrine pancreatic insufficiency, including cystic fibrosis, chronic pancreatitis, pancreatic tumors, or pancreatectomy.

Pancreatic extract drug products have been marketed in the United States for many years. Marketing of some versions of these products predates the 1938 passage of the Federal Food, Drug, and Cosmetic Act (the act). Over the years, other pancreatic extract drug products have entered the market. Various dosage forms of pancreatic enzyme drug products are currently marketed as prescription drug products: Uncoated tablets, powders, capsules, enteric-coated tablets, and encapsulated enteric-coated microspheres.

Some pancreatic extract drug products were marketed over-the-counter (OTC). As part of the OTC drug review, FDA evaluated the safety and effectiveness of drug products used to treat exocrine pancreatic insufficiency. FDA's review of data and information on pancreatic extract drug products found significant variations in bioavailability among the various dosage forms and among products from different manufacturers of the same dosage form. Available data have shown that the formulation, dosage, and manufacturing process of pancreatic enzyme drug products have a critical effect on the safe and effective use of these drugs. FDA concluded that preclearance of each product to standardize enzyme bioactivity would be necessary. FDA also determined that continuous physician monitoring of patients is a collateral measure necessary to the safe and effective use of pancreatic enzyme drug products, requiring that these products be available by prescription only and that the products be approved through the new drug approval process to standardize enzyme activity (56 FR 32282, July 15, 1991; 60 FR 20162, April 24, 1995).

The 2004 notice reiterated FDA's determination that all pancreatic extract drug products are new drugs under section 201(p) of the act (21 U.S.C. 321(p)), requiring approved NDAs under section 505 of the act (21 U.S.C. 355) and 21 CFR part 314. The document stated that FDA expects to receive only NDAs, including applications submitted under section 505(b)(2) of the act, for these products. To assist manufacturers of pancreatic extract drug products in preparing and submitting documentation to meet NDA requirements for the drug products, FDA announced the availability of a draft guidance for industry entitled ''Exocrine Pancreatic Insufficiency Drug Products—Submitting NDAs'' in the **Federal Register** of April 28, 2004 (69

FR 23414). In response, FDA received a number of comments which the agency considered in finalizing the guidance. In the **Federal Register** of April 14, 2006 (71 FR 19524), FDA announced the availability of the final guidance (available on the Internet at *http://www.fda.gov/cder/guidance/index.htm*).

FDA stated in the 2004 notice that pancreatic extract drug products are used to treat exocrine pancreatic insufficiency, a condition in which symptoms are due to deficient secretion of pancreatic enzymes (i.e., lipase, protease, amylase) essential for normal digestion and absorption, and no alternative drug is relied upon by the medical community to treat the lack of lipase, protease, and amylase caused by exocrine pancreatic insufficiency. The severity of the conditions varies from patient to patient as does the dosage requirement of pancreatic enzyme replacement therapy needed to relieve the symptoms of pancreatic insufficiency.

Pancreatic enzyme therapy is a daily requirement for patients with exocrine pancreatic insufficiency and is needed for survival for many of these patients (e.g., cystic fibrosis patients). The appropriate daily dose of pancreatic enzymes must be individualized and adjusted when clinically indicated. To meet the needs of patients requiring pancreatic enzyme replacement therapy, drug products with varying dosage forms, enzyme content, and activity need to remain available for patient use. Only one product, Cotazym, sponsored by Organon, Inc., is the subject of an approved NDA and that product is not currently being marketed.

The 2004 notice advised that FDA intended to exercise its enforcement discretion until April 28, 2008, as to unapproved pancreatic enzyme drug products that were marketed on or before April 28, 2004. FDA determined that pancreatic enzyme drug products are medically necessary and, accordingly, FDA intended to exercise its enforcement discretion so that pancreatic extract drug products would remain available during the period necessary for manufacturers to conduct the required studies, prepare applications, and have the applications approved.

This provision for the exercise of enforcement discretion applied only to pancreatic enzyme products marketed on or before the publication of the April 28, 2004, **Federal Register** document. The document stated that after April 28, 2008, any pancreatic enzyme drug product that is introduced or delivered for introduction into interstate commerce without an approved application will be subject to regulatory action, unless there has been a finding by FDA under a citizen petition submitted for that product that the product is not subject to the new drug requirements of the act. The deadline for filing a citizen petition was June 28, 2004. No one submitted a citizen petition in response to the 2004 notice.

In response to the 2004 notice, a number of manufacturers of pancreatic extract drug products have indicated that they need an extension of time to obtain approved applications. The manufacturers contend that additional time is needed because of numerous problems encountered during the drug development process, predominantly manufacturing issues, and difficulty conducting all of the required studies needed for NDA filing and approval.

The agency has carefully considered the requests and concludes that additional time is justified to ensure the continued availability of pancreatic extract drug products after April 28, 2008. As these pancreatic extract drugs are naturally-derived products of porcine origin, manufacturers must conform with currently accepted standards for protein therapeutic products. The justification for this extension is based upon chemistry, manufacturing, and control issues that previously have not been well-understood and have been found to be particularly challenging for these enzyme preparations derived from porcine pancreas. These issues include the following:

- Control and evaluation of variability of pancreatic source materials used in drug substance manufacture;
- Measurement of viral loads, viral inactivation, and resultant risk assessment and mitigation strategies as described in International Conference on Harmonisation guidance Q5A;
- Development and implementation of validated purity and identity drug substance and product release and stability testing methodologies for the very complex protein mixtures derived from porcine pancreas;
- Required modification and validation of the traditional lipase potency assay methodology based upon recent scientific studies; and
- Maintenance and confirmation of drug product stability without the use of overages to increase the dating period.

By this notice, FDA is extending the period during which it intends to exercise its enforcement discretion as to certain unapproved pancreatic enzyme products until April 28, 2010.

This extension of the period during which FDA intends to exercise its enforcement discretion applies to any manufacturer of pancreatic extract drug products marketed on or before publication of the 2004 notice, if the manufacturer has an active IND for its pancreatic extract product on or before April 28, 2008, has submitted an NDA on or before April 28, 2009, and is pursuing approval of its application with due diligence as determined by FDA. In determining the due diligence of an applicant, FDA will examine the facts and circumstances of the applicant's actions during the drug development and review period to determine whether the applicant exhibited the degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, an applicant during this period. FDA will take into consideration whether the applicant is conducting its clinical trials in a manner and at a rate sufficient for NDA submission on or before April 28, 2009, the adequacy and completeness of any required or necessary documents submitted by the applicant to FDA, the speed and thoroughness with which the applicant responds to any FDA requests for information or notifications of deficiencies, and any other relevant evidence of whether the applicant is making a genuine effort to meet the deadlines set out in this notice and obtain FDA approval for its products.

FDA believes that establishing certain milestones will ensure that manufacturers are actively pursuing an NDA approval. Under those circumstances, extending the period of enforcement discretion as described in this notice will provide sufficient time for manufacturers to obtain approval of NDAs. Therefore, the agency does not anticipate that any further extensions will be needed. The agency, however, does not intend to exercise its enforcement discretion as described in this notice if the following conditions exist: (1) A person manufacturing or shipping an unapproved product covered by this notice is violating other provisions of the act or (2) there is significant new information related to a safety risk associated with a specific product covered by this notice.

FDA intends to take regulatory action, including but not limited to initiating seizure, injunction, or other judicial or administrative proceedings, against manufacturers that are marketing unapproved pancreatic insufficiency drug products and are not actively pursuing approval. Actively pursuing approval means that the manufacturer has an active IND on or before April 28, 2008, and has submitted an NDA on or

before April 28, 2009.[1] The agency may choose not to issue a warning letter or any further warning prior to taking a regulatory action against a firm that is marketing an unapproved exocrine pancreatic insufficiency drug product and not actively pursuing approval.

This notice is issued under sections 502 and 505 of the act (21 U.S.C. 352) and under authority delegated to the Assistant Commissioner for Policy.

Dated: October 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–21082 Filed 10–25–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0364]

Draft Guidance for Industry and Food and Drug Administration Staff; Impact-Resistant Lenses: Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Impact-Resistant Lenses: Questions and Answers.'' This draft guidance document answers manufacturer, importer, and consumer questions on impact-resistant lenses, including questions on test procedures, lens testing apparatus, record maintenance, and exemptions to testing.

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 January 24, 2008.

ADDRESSES: Submit written requests for single copies of the guidance document entitled''Impact-Resistant Lenses: Questions and Answers'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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 either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: John Stigi, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–3150.

SUPPLEMENTARY INFORMATION:

I. Background

Eyeglasses and sunglasses are medical devices and are subject to device regulations, including § 801.410 (21 CFR 801.410). This draft guidance document revises the original guidance document entitled ''Impact-Resistant Lenses: Questions and Answers'' (FDA 87–4002), issued September 1987. This draft guidance document also contains detailed and updated discussions of the following: (1) Lens blanks; (2) semi-finished, finished, and plano lenses; and (3) import entry inspections.

To reduce the number of eye injuries, eyeglasses and sunglasses must be fitted with impact-resistant lenses capable of withstanding the impact test described under § 801.410(d)(2). This draft guidance answers questions for manufacturers, importers, and testing laboratories on such topics as test procedures, lens testing apparatus, record maintenance, and exemptions to testing.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on impact-resistant lenses. 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 and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''Impact-Resistant Lenses: Questions and Answers,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number (23) to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. 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 801.109 have been approved under OMB Control No. 0910–0485; the collections of information in 21 CFR 807.87 have been approved under OMB Control No. 0910–0120; and the collections of information in 21 CFR part 820 have been approved under OMB Control No. 0910–0073.

V. 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.

[1] If FDA decides to take enforcement action against a firm's unapproved exocrine pancreatic insufficiency drug product, the agency may at the same time take action relating to any and all of the firm's other violations. For example, if a firm continues to market an unapproved exocrine pancreatic insufficiency drug product but fails to actively pursue approval, to preserve limited agency resources, FDA may take enforcement action relating to any and all of the firm's other unapproved drugs that require applications (see, e.g., *United States* v. *Sage Pharmaceuticals*, 210 F. 3d 475, 479–480 (5th Cir. 2000) (permitting the agency to combine all violations of the act in one proceeding, rather than taking action against multiple violations of the act in ''piecemeal fashion'')).