applications may also include quality-by-design approaches to multiple unit operations and the stage of product development. For original applications, it would be of value to enter the pilot well in advance of submitting the application. Entry during the appropriate stage of development, as an investigational new drug (IND), would facilitate working with the agency on quality-by-design approaches.

Because the number of biotechnology product applications submitted is relatively low compared to small-molecule drugs, the pilot will have an extended submission period. Written requests to participate in this pilot program for products regulated by OBP may be submitted from the date of the publication of this notice until September 30, 2009. This pilot program will be limited to 10 supplements to be submitted by March 31, 2010, and 5 original applications for products reviewed by OBP (BLA or NDA) in Common Technical Document (CTD) format, paper or electronic. As noted in the previous paragraph, it is preferable for original applications to enter the pilot as INDs. The INDs must be submitted before March 31, 2010. Due to resource considerations, participation in the program may be limited to a total of three pilot submissions to OBP per quarter.

Every effort will be made to ensure that a variety of pharmaceutical companies and complex biotechnology product types are included in this pilot program. This pilot affects the CMC section of the submission; however, supportive data may relate to other disciplines. Existing regulations and requirements for the submission of a supplement or marketing application (BLA or NDA) will not be waived, suspended, or modified for purposes of this pilot program. Participants must submit the application supplement or original application, paper or electronic, in accordance with 21 CFR parts 314 and 601 and other relevant regulations.

B. Process and How to Request Participation in the Pilot

Interested parties should submit to the Division of Dockets Management (see **ADDRESSES**) a written request to participate in the pilot program (identified with the docket number found in brackets in the heading of this document). The request should include the following information: (1) The contact person's name, company name, company address, and telephone number; (2) the name of the drug product and a brief description of the drug substance, dosage form, indication, and stage of development; (3) a summary of the approaches that define relevant attributes and process parameters; (4) a statement describing the manufacturing changes to be included in an Expanded Change Protocol; and (5) a timeline for requested premeetings and for the submission. All pharmaceutical companies requesting participation in the pilot program will be notified of their acceptance in writing by OBP within 60 days of receipt of the request.

Potential participants are encouraged to discuss their plans to participate in this pilot program with OBP. Discussions with potential applicants can facilitate appropriate pilot applications. Meeting requests for potential applicants should be submitted in accordance with FDA's guidance for industry on ''Formal Meetings With Sponsors and Applicants for PDUFA Products,'' February 2000 (*http://www.fda.gov/cder/guidance/2125fnl.htm*). Once an application is selected for participation in this program, the applicant can meet with OBP as needed before the submission and during the review process by sending requests directly to OBP.

The quality assessment under this pilot program will be conducted under the direct oversight of the OBP Office Director by a team of experienced OBP scientists who have a strong scientific background in product quality, biochemistry, biology and structure/function relationships. OBP will be assisted by the Office of Compliance on proposed current good manufacturing practices (CGMP) and facility approaches and other disciplines, as appropriate. ONDQA and FDA's Center for Biologics Evaluation and Research will also coordinate with OBP to facilitate a consistent general approach to quality-by-design principles.

After the application or amendment has been submitted into the pilot program, the submission may be withdrawn or amended within an agreed upon timeframe to not delay approval.

III. 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.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: June 24, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–14999 Filed 7–1–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1986–F–0277] (formerly Docket No. 1986F–0364)

Danisco USA, Inc.; Withdrawal of Food Additive Petition; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 6A3958) that appeared in the **Federal Register** of June 20, 2008. FDA is correcting the addresses of both Pfizer, Inc., and Danisco USA, Inc.

DATES: This correction is effective July 2, 2008.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Regulations Editorial Section (HF–27), Food and Drug Administration, 5600 Fishers Ln., Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. E8–13998, published on June 20, 2008 (73 FR 35142), the following corrections are made:

1. On page 35143, in the first column, in the **SUPPLEMENTARY INFORMATION** section, the address for Pfizer, Inc., is corrected to read ''235 East 42d St., New York, NY 10017''.

2. Also on page 35143, in the first column, in the **SUPPLEMENTARY INFORMATION** section, the address for Danisco USA, Inc., is corrected to read ''565 Taxter Rd., suite 590, Elmsford, NY 10523''.

Dated: June 26, 2008.

Laura M. Tarantino,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. E8–14998 Filed 7–1–08; 8:45 am]

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