using a peer review process that is fair, unbiased from outside influence, timely, and (4) To develop new modes of operation based on customer need and customer feedback about the efficacy of implemented modifications. These surveys will almost certainly lead to quality improvement activities to enhance and/or streamline CSR's operations. The major mechanism by which CSR will request input is through surveys. The major initiatives ongoing at the present time include: shortening the review and application process, shortening the grant application, recruiting the best reviewers by developing additional review modes, improving study section alignment to ensure the best reviews, and others. Surveys will be collected via Internet. Information gathered from these surveys will be presented to, and used directly by, CSR management to enhance the operations, processes, organization of, and services provided by the Center.

Frequency of Response: The participants will respond once, unless there is a compelling reason for a subsequent survey.

Affected public: Universities, not-for-profit institutions, business or other for-profit, small businesses and organizations, and individuals.

Type of Respondents: Adult scientific professionals.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Instrument/Activity	Annual number of respondents	Number of responses per respondent	Annual average burden per response	Total burden hours per annual collection
Focus Groups	75	1	2.5 hours	187.5 hours
Mail/telephone/e-mail Surveys	5,000	1	0.25 hours	1,250 hours
Annual Total	5,075	.....	.....	1,437.5 hours per year

Requests for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the CSR, including whether the information will have practical utility; (2) The accuracy of the agency'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 of information on those who are to respond while maintaining their anonymity, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov*, or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Andrea Kopstein, Director of Planning, Analysis, and Evaluation, Center for Scientific Review, NIH, Room 3030, 6701 Rockledge Drive, Bethesda, MD 20892–7776, or call non-toll-free number 301–435–1133 or E-mail your request, including your address to: *kopsteina@csr.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: June 23, 2008.

Andrea Kopstein,

Director of Planning, Analysis, and Evaluation, CSR, National Institutes of Health.

[FR Doc. E8–14920 Filed 7–1–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; American Health Information Community Meeting

ACTION: Meeting announcement.

SUMMARY: This notice announces the meeting date for the 23rd meeting of the American Health Information Community in accordance with the Federal Advisory Committee Act (Pub. L. No. 92–463, 5 U.S.C., App.) The American Health Information Community will advise the Secretary and recommend specific actions to achieve a common interoperability framework for health information technology (IT).

Meeting Date: July 29, 2008, from 8:30 a.m. to 2 p.m. (Eastern).

ADDRESSES: Hubert H. Humphrey building (200 Independence Avenue, SW., Washington, DC 20201), Conference Room 800.

SUPPLEMENTARY INFORMATION: The meeting will include an update on the AHIC Successor organization; a discussion on the health information technology Strategic Plan; and an update on clinical research and health IT.

FOR FURTHER INFORMATION CONTACT: Visit *http://www.hhs.gov/healthit/ahic.html*.

A Web cast of the Community meeting will be available on the NIH Web site at: *http://www.videocast.nih.gov/*. If you have special needs for the meeting, please contact (202) 690–7151.

Dated: June 24, 2008.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. E8–15007 Filed 7–1–08; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0355]

Submission of Quality Information for Biotechnology Products in the Office of Biotechnology Products; Notice of Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is seeking volunteers from pharmaceutical companies to participate in a pilot

program involving the submission of quality (chemistry, manufacturing, and controls) information for biotechnology products in an Expanded Change Protocol, consistent with the principles of quality by design and risk management in pharmaceutical manufacturing. The purpose of the pilot program is to gain more information on and facilitate agency review of quality-by-design, risk-based approaches for manufacturing biotechnology products. This pilot will focus on products reviewed by FDA's Office of Biotechnology Products (OBP), in the Office of Pharmaceutical Science (OPS), Center for Drug Evaluation and Research (CDER). This pilot program will assist FDA in developing guidance for industry on quality by design and risk management in pharmaceutical manufacturing. The pilot is open to original submissions of and supplements to biologic license applications (BLA) or new drug applications (NDA) reviewed by OBP.

DATES: Submit written and electronic requests to participate in the pilot program by September 30, 2009. Comments on this pilot program can be submitted until December 31, 2008.

ADDRESSES: Submit written requests to participate in and to comment on the pilot program to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic requests to participate in the pilot to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Marilyn Welschenbach, Center for Drug Evaluation and Research, Food and Drug Administration,Bldg. 21, rm. 1514, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002,301–796–1773, e-mail: *Marilyn.Welschenbach@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

OPS, in FDA's CDER, is establishing a quality-by-design, risk-based approach to pharmaceutical quality, which is based on FDA's final report on ''Pharmaceutical cGMPs for the 21st Century—A Risk-Based Approach'' (*http://www.fda.gov/cder/gmp/gmp2004/GMP_finalreport2004.htm*). The new quality-by-design approach will focus on critical quality attributes related to chemistry, formulation, and process design. Under quality by design, manufacturing will depend on a risk-based approach linking attributes and processes to product performance, safety, and efficacy.

The principles underlying this new approach to a quality-by-design, risk-based assessment can be found in the International Conference on Harmonisation (ICH) guidances: ''Q8 Pharmaceutical Development,'' May 2006 (*http://www.fda.gov/cder/guidance/6746fnl.pdf*), and ''Q9 Quality Risk Management (ICH),'' June 2006 (*http://www.fda.gov/cder/guidance/7153fnl.pdf*), and FDA's guidances for industry entitled ''PAT— A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance,'' September 2004 (*http://www.fda.gov/cder/guidance/6419fnl.pdf*), and ''Quality Systems Approach to Pharmaceutical CGMP Regulations,'' September 2006 (*http://www.fda.gov/cder/guidance/7260fnl.pdf*). Quality-by-design and risk-based approaches are also described in the following draft guidances: ''Q8(R1) Pharmaceutical Development Revision 1'' (*http://www.fda.gov/cder/guidance/8084dft.pdf*) and ''Q10 Pharmaceutical Quality Systems'' (*http://www.fda.gov/cder/guidance/7891dft.pdf*).

The agency's Office of New Drug Quality Assessment (ONDQA) in OPS, CDER, initiated a pilot program (70 FR 40719, July 14, 2005) to gain experience in assessing chemistry, manufacturing, and controls (CMC) sections of NDAs that demonstrate an applicant's product knowledge and process understanding at the time of submission. This pilot was extremely useful in helping identify appropriate information to be shared regarding quality by design for small molecules. Although many of the principles of quality by design apply equally to small molecules and more complex pharmaceuticals, the ability to assess relevant attributes is a much greater challenge for complex pharmaceuticals.

The OBP pilot described in this document focuses on defining clinically relevant attributes for complex products and linking them to the manufacturing process. In addition to considering quality by design for an entire original application, this pilot also will consider quality-by-design approaches to unit operations in supplements. Finally, this pilot will explore the use of protocols submitted under §§ 314.70(e) and 601.12(e) (21 CFR 314.70(e) and 601.12(e)).

Sections 314.70 and 601.12(e) allow for the use of protocols describing the specific tests and studies and acceptance criteria to be achieved to demonstrate the lack of adverse effect for specified types of manufacturing changes on the identity, strength, quality, purity, and potency of the drug product. A particular type of protocol is a Comparability Protocol. In many cases, Comparability Protocols have been used for a single manufacturing change. Protocols based on quality-by-design submissions will focus on critical quality attributes related to chemistry, formulation, and process design. Such protocols will be referred to as Expanded Change Protocols. Expanded Change Protocols will describe the quality-by-design, risk-based approach linking attributes and processes to product performance, safety, and efficacy.

II. Description of Pilot Program

This pilot will focus on quality-by-design approaches to the manufacturing of biotechnology products through the use of Expanded Change Protocols. The pilot program will provide additional information to FDA for use in facilitating quality-by-design, risk-based approaches for complex molecules. OBP will work with each participant on an individual basis. Pilot submissions will be either original applications or manufacturing supplements subject to the Prescription Drug User Fee Act (PDUFA) Performance Goals; we expect that participation in the pilot program will not adversely affect our ability to meet the review goal. The process will include appropriate coordination between agency quality review staff and staff from other disciplines (such as compliance, clinical pharmacology, toxicology, clinical review, as needed) based on the scope of the submission. Based on experience gained during the pilot program and prior knowledge, FDA will develop procedures to facilitate implementing a quality-by-design, risk-based approach for complex products. In addition, the experience gained by FDA under this pilot is expected to facilitate the development of guidance for industry.

A. Scope

The pilot program will include both original applications and postapproval supplements. A pilot program submission should demonstrate the applicant's increased knowledge of product attributes and link the product attributes to process parameters in an Expanded Change Protocol. Acceptance into this pilot program will depend on the soundness of the applicant's proposal as described in their written request to participate in the pilot and the potential of the proposed application to affect the development of a quality-by-design, risk-based approach for complex products. Considerations for acceptance into the pilot may include sponsor approaches to risk management and use of prior knowledge. Considerations for original

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]

BILLING CODE 4160–01–S