Part III of the proposed order prohibits Respondent from making misrepresentations in advertising for any morning food or snack food about the existence, contents, validity, results, conclusions, or interpretations of any test, study or research.

Part IV of the proposed order states that the order does not prohibit Respondent from making representations for any product that are specifically permitted in labeling for that product by regulations issues by the FDA under the Nutrition Labeling and Education Act of 1990.

Parts V through VIII of the proposed order require Respondent to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to certain of their personnel; to notify the Commission of changes in corporate structure that might affect compliance obligations under the order; and to file compliance reports with the Commission. Part IX provides that the order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

Donald S. Clark

Secretary.

[FR Doc. E9–9484 Filed 4–24–09: 8:45 am]

BILLING CODE 6750–01–S

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0044]

Public Buildings Service; Information Collection; GSA Form 3453, Application/Permit for Use of Space in Public Buildings and Grounds

AGENCY: Public Buildings Service, GSA.

ACTION: Notice of request for comments regarding a renewal to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the General Services Administration will be submitting to the Office of Management and Budget (OMB) a request to review and approve a renewal of a currently approved information collection requirement regarding GSA Form 3453, Application/Permit for Use of Space in Public Buildings and Grounds. The clearance currently expires on April 30, 2009.

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected.

DATES: Submit comments on or before: June 26, 2009.

FOR FURTHER INFORMATION CONTACT: Frank Giblin, Public Buildings Service, at telephone (202) 501–1856, or via e-mail to *frank.giblin@gsa.gov.*

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Regulatory Secretariat (VPR), General Services Administration, Room 4041, 1800 F Street, NW., Washington, DC 20405. Please cite OMB Control No. 3090–0044, GSA Form 3453, Application/Permit for Use of Space in Public Buildings and Grounds, in all correspondence.

SUPPLEMENTARY INFORMATION:

A. Purpose

The general public uses GSA Form 3453, Application/Permit for Use of Space in Public Buildings and Grounds, to request the use of public space in Federal buildings and on Federal grounds for cultural, educational, or recreational activities. A copy, sample, or description of any material or item proposed for distribution or display must also accompany this request.

B. Annual Reporting Burden

Respondents: 8,000.

Responses per Respondent: 1.

Hours per Response: 0.05.

Total Burden Hours: 400.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (VPR), 1800 F Street, NW., Room 4041, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 3090–0044, GSA Form 3453, Application/Permit for Use of Space in Public Buildings and Grounds, in all correspondence.

Dated: April 21, 2009.

Philip E. Klokis,

Acting Chief Information Officer.

[FR Doc. E9–9490 Filed 4–24–09; 8:45 am]

BILLING CODE 6820–YT–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0179]

Draft Guidance for Industry and Food and Drug Administration Staff: Technical Considerations for Pen, Jet, and Related Injectors Intended for Use With Drugs and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products.'' The draft guidance document provides technical and scientific information for sponsors to consider in developing information to support a marketing application for a pen, jet, or related injector device intended for use with drugs or biological products. The marketing application would typically be a premarket notification submission (510(k)) or a premarket approval (PMA) application for the injector alone. For a combination product that includes the injector, the marketing application would typically be a new drug application (NDA) or a biological licensing application (BLA).

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 July 27, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Combination Products, 15800 Crabbs Branch Way, Rockville, MD 20855. 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 the Office of Combination Products at 301–427–1934 or by e-mail to *combination@fda.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.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Patricia Y. Love, Office of Combination Products (HFG–3), Food and Drug Administration, 15800 Crabbs Branch Way, Rockville, MD 20855, 301–427–1934.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products.'' FDA is providing this draft guidance document to assist industry in developing technical and scientific information to support a marketing application for a pen, jet, or related injector device. The marketing application would typically be a 510(k) or a PMA application for the injector alone. For a combination product that includes the injector, the marketing application would typically be an NDA or a BLA. For purposes of this guidance, the term ''injector'' includes, but is not limited to, jet injectors, pen injectors, piston syringes, needle-free injectors, mechanically operated injectors, and injectors with computerized or electronic elements.

II. Significance of Guidance

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 the agency's current thinking on ''Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products.'' 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.

III. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that 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 807 have been approved under OMB control number 0910–0120. The collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information 21 CFR part 601 have been approved under OMB control number 0910–0338.

IV. 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.

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/oc/combination/* or *http://www.regulations.gov*.

Dated: April 20, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–9519 Filed 4–24–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Healthy Start Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: General notice.

SUMMARY: Following the Senate Appropriations Committee's recommendation, the Health Resources and Services Administration (HRSA) will give funding preference during the FY 2009 competition to current and former Healthy Start grantees with expiring or recently expired project periods.

BACKGROUND: This notice supplements the 2008 HRSA announcement (HRSA 09–130 and 09–131) of the availability of fiscal year (FY) 2009 funding for new and competing continuation applications for Healthy Start. Healthy Start, authorized under Section 330H of the Public Health Service Act, strengthens communities to effectively address the causes of infant mortality, low birth weight and other poor perinatal outcomes for women and infants. Recently, new guidance became available with regard to funding FY 2009 Healthy Start programs.

This new guidance continues guidance from Congress that began in FY 2002. During the FY 2001 Healthy Start Initiative: Eliminating Disparities in Perinatal Health Open Competition, several grantees were approved but unfunded. Subsequently, Congress noted that the phasing out of these grants would cause a major disruption in services for pregnant women and infants in communities with high infant mortality and poor perinatal outcomes. For FY 2002, Congress, under The Consolidated Appropriations Act of 2002 (Pub. L. 107–116), Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2002, allocated additional funding for these grants but stipulated that these new funds were to be used to ''give preference to current and former grantees with expiring or recently expired project periods, including grantees that did not receive funding but whose grant applications were approved but not funded during fiscal year 2001.'' HRSA honored this request and funded the remaining approved unfunded grantee applicants in February 2002.

This preference language has continued in each Healthy Start competition since 2002. With the 2005 Healthy Start competition, Congress, through The Consolidated Appropriations Act (Pub. L. 108–447, HR 108–792), once again gave ''preference to current and former grantees with expiring or recently expired project periods.'' In 2006, the Conference report HR 109–200, accompanying the Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriation Act, 2006, (Pub. L. 109–149, HR 109–300) continued the preference language. This year's FY 2009 Senate Appropriations Committee report states that ''The healthy start initiative was developed to respond to persistently high rates of infant mortality in this Nation. The initiative was expanded in fiscal year 1994 by a special projects program, which supported an additional seven urban and rural communities to implement infant mortality reduction strategies and interventions. The Children's Health Act of 2000 fully authorized this initiative as an independent program. The Committee urges HRSA to give preference to current and former grantees with expiring or recently expired project periods.'' (S. Rept. 110–410)