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FDA is announcing the availability of a draft guidance document entitled ''Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products.'' FDA is providing this draft guidance document to assist industry in developing technical and scientific information to support a marketing application for a pen, jet, or related injector device.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The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on ''Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and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This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995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The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time.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)

FOR FURTHER INFORMATION CONTACT: Maribeth Badura, Director, Division of Healthy Start and Perinatal Services, Maternal and Child Health Bureau, HRSA, Room 18–12, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443–0543; e-mail *MBadura@hrsa.gov*.

Dated: April 21, 2009.

Marcia K. Brand,

Deputy Administrator.

[FR Doc. E9–9517 Filed 4–24–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0430] (formerly Docket No. 2007D–0166)

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Guidance for Industry on ''Target Animal Safety for Veterinary Pharmaceutical Products,'' VICH GL43; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#185) entitled ''Target Animal Safety for Veterinary Pharmaceutical Products,'' VICH GL43. The purpose of this harmonized guidance is to provide recommendations regarding target animal safety (TAS) evaluation for regulatory submission of an Investigational Veterinary Pharmaceutical Product (IVPP), which is appropriate for determining the safety of an IVPP in the target animal. The guidance includes recommendations on including identification of target organs, where possible, and confirmation of margin of safety, using the minimum number of animals appropriate for the studies.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Steven Vaughn, Center for Veterinary Medicine, (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8300, e-mail: *steven.vaughn@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use (VICH) for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency, European Federation of Animal Health, Committee on Veterinary Medicinal Products, the U.S. FDA, the U.S. Department of Agriculture, the Animal Health Institute, the Japanese Veterinary Pharmaceutical Association, the Japanese Association of Veterinary Biologics, and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

II. Guidance on Target Animal Safety for Veterinary Pharmaceutical Products

In the **Federal Register** of May 18, 2007 (72 FR 28058), FDA published the notice of availability for a draft guidance entitled ''Draft Guidance for Industry on Target Animal Safety for Veterinary Pharmaceutical Products,'' which gave interested persons until June 18, 2007, to comment on the draft guidance. FDA received a few comments on the draft guidance and those comments as well as those received by other VICH member regulatory agencies were considered as the guidance was finalized. Based on the comments received, the VICH Expert Working Group on Target Animal Safety clarified the guidance's recommendations regarding the development and conduct of TAS studies. In particular, the Expert Working Group revised the sections addressing necropsy and histopathology examinations and mammary gland studies to clarify the recommendations regarding these topics. At a meeting held in July 2008, the VICH Steering Committee endorsed the final guidance for industry, (VICH GL43). The guidance announced in this notice finalizes the draft guidance dated May 18, 2007.

This guidance document is intended to cover TAS evaluation for any IVPP used in the following species: Bovine, ovine, caprine, feline, canine, porcine, equine, and poultry (chickens and turkeys). The recommendations in this guidance may not be appropriate for registration by national or regional authorities of products for use in minor species or minor uses. The guidance does not provide information for the design of TAS studies in other species, including aquatic animals. For other species and for minor uses, TAS studies should be designed following national or regional guidance.

III. Significance of Guidance

This guidance document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated ''guidance'' rather than