4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0179]

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 final guidance document entitled "Technical Considerations for Pen, Jet, and Related Injectors Intended for Use With Drugs and Biological Products," dated June 2013. The final 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). The guidance announced in this notice finalizes the draft guidance of the same title dated April 2009 and published under Docket No. FDA-2009-D-0179.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32,

rm. 5129, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling the Office of Combination Products at 301-796-8930. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Patricia Y. Love, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry and FDA Staff: Technical Considerations for Pen, Jet, and Related Injectors Intended for Use With Drugs and Biological Products" dated June 2013. FDA is providing this final 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.

In the Federal Register on April 27, 2009, (74 FR 19094), FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. The final guidance is largely similar to the draft guidance. The significant changes to the guidance include: Additional information to clarify the bases for the technical and scientific recommendations for general use injectors, injectors intended for a class/family of drugs or biological products, injectors intended for a sponsor's product line, and injectors for use with a specific drug or biological product. The guidance provides additional information to assist developers in considering the relevance of already approved drug or biological product labeling in the development of injectors intended for general use or for use with a class/family or product line, which should assist in developing labeling for the injectors. The document provides links to other Agency documents published since the April 2009 draft guidance. Also, the document contains editorial and terminology changes to improve clarity and readability. The guidance announced in this notice finalizes the draft guidance dated April 2009.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review and have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 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 in 21 CFR part 601 have been approved under OMB control number 0910-0338.

III. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either http://www.fda.gov/CombinationProducts/default.htm or http://www.regulations.gov

Dated: May 31, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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