EPSTEIN BECKER GREEN | HEALTH CARE & LIFE SCIENCES CLIENT ALERT

Thought Leaders in Health Law®

New FDA Draft Guidance on Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products

by Brad Thompson, Wendy C. Goldstein, Leah Kendall
May 2009

On April 27, 2009, the U.S. Food & Drug Administration **("FDA")** announced the availability of a new draft guidance document titled "Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products" **("Draft Guidance")**.[1] The Draft Guidance is available at: http://www.fda.gov/oc/combination/guidance_injectors.pdf. The Draft Guidance covers a wide array of products and topics. It is of particular significance to companies that develop and manufacture therapeutic products administered by pen, jet and other types of injectors, as well as to medical device manufacturers that develop and make injectors. Comments should be submitted to the FDA by **July 27, 2009,** in order to ensure that they are reviewed before the FDA begins finalizing the Draft Guidance.[2]

This Alert provides an overview of the Draft Guidance and highlights some of the key areas for potential comment.

OVERVIEW OF THE DRAFT GUIDANCE

Scope

The Draft Guidance casts a wide net to a broad array of products–both combination products incorporating an injector as well as general use device injectors. Specifically, the scope of the Draft Guidance includes pen, jet, and related injector devices. Further, "injector" includes jet injectors, pen injectors, piston syringes, needle-free injectors, mechanically operated injectors, and injectors with computerized or electronic elements.

These injectors may consist of stand-alone, general use injectors, and injectors intended for a product class, product line, or a specifically named drug or biological product. In other words, the Draft Guidance extends to combination products of which a device injector is a constituent part, and to general use device injectors that are not combination products. As a consequence of this broad scope, the Draft Guidance could have particularly significant ramifications for applicants that submit marketing submissions for

general use device injectors.

Technical and Scientific Issues for Injectors

The Draft Guidance addresses technical and scientific issues to be considered when developing injectors intended for use with drugs or biological products. It also provides content and format information for injectors to be reviewed under 510(k) submissions and for review as part of a New Drug Application (NDA) or Biologics License Application (BLA). Specifically, the Draft Guidance focuses on scientific and technical information for the injector that would be part of any marketing application. According to the FDA, the Draft Guidance "is intended to promote efficient premarket review and ensure consistent and appropriate postmarket regulation of injector delivery systems."[3]

Policy Considerations

Although the Draft Guidance is primarily focused on the scientific and technical considerations associated with the development and approval of injectors, it also implicates important policy questions. By way of example, the Draft Guidance states that it does not address the appropriate type of marketing application for injector combination products or the number of applications required for approval. However, the Draft Guidance does, in fact, include language regarding "typical" applications for general use injectors and combination products that incorporate an injector constituent part. The Draft Guidance also recognizes that the FDA "may determine" that more than one application is needed for such products. In this regard, the Draft Guidance provides detailed information on the content requirements of an application for an injector or incorporating an injector, without first addressing fundamental questions about the type or number of application(s) required.

Another example of policy considerations implicated by the Draft Guidance is relevant to clinical trial design. Specifically, while the Draft Guidance notes that specific considerations for clinical trial design is beyond its scope, it raises important questions about requirements for clinical data. For instance, the Draft Guidance states that "clinical trials for some injectors may focus on the injector itself" without acknowledging instances in which clinical trials may not be required or where simulated use studies may be preferred.

CONSIDERATIONS

Manufacturers should consider the legal ramifications and operational issues presented by the Draft Guidance, including the following areas:

- The scope of products included under the Draft Guidance;
- The information set forth in the Draft Guidance relating to marketing applications for products incorporating injectors and for injectors themselves;
- The clinical data and clinical study design requirements; and
- The areas on which the Draft Guidance does not provide direction or provides limited direction. By way of example, such areas include the number and type of marketing submissions, the way in which an injector's composition influences the regulatory

requirements that apply, and the requirements pertaining to post-market modifications made to injectors or products incorporating an injector.

* * *

For questions regarding this alert and topic, please contact:

Brad Thompson
Washington, DC
(202) 861-1817
Bthompson@ebglaw.com

Wendy C. Goldstein
New York
(212) 351-3737
Wgoldstein@ebglaw.com

Leah Kendall
Washington, DC
(202) 861-4197
Lkendall@ebglaw.com

The EpsteinBeckerGreen Client Alert is published by EBG's Health Care and Life Sciences practice to inform health care organizations of all types about significant new legal developments.

Lynn Shapiro Snyder, Esq.
EDITOR

If you would like to be added to our mailing list or need to update your contact information, please contact, Jennifer Sunshine, Jsunshine@ebglaw.com or 202/861-1872.

[1] 74 Fed Reg. 19094, *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* (Apr. 27, 2009).
[2] FDA regulations allow for public comment on guidance documents at any time.
[3] *See* note 1.