Docket No. FDA-2013-N-1038

COMMENTS

of

THE WASHINGTON LEGAL FOUNDATION

to the

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH & HUMAN SERVICES

Concerning

OVER-THE-COUNTER OPHTHALMIC DRUG PRODUCTS – INFORMATION ON THE FORMULATION, MANUFACTURING, AND LABELING OF CURRENTLY MARKETED OVER-THE-COUNTER EMERGENCY USE EYEWASH PRODUCTS

IN RESPONSE TO THE PUBLIC NOTICE PUBLISHED
AT 78 *FED. REG.* 57397 (SEPTEMBER 18, 2013)

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March 7, 2014

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Via Email
Division of Dockets Management (HFA-305)
Food and Drug Administration
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Re: Over-the-Counter Ophthalmic Drug Products — Information on the Formulation, Manufacturing, and Labeling of Currently Marketed Over-the-Counter Emergency Eyewash Products
78 Fed. Reg. 57397 (September 18, 2013)
Docket No. FDA-2013-N-1039

Dear Sir/Madam:

The Washington Legal Foundation (WLF) appreciates this opportunity to submit written comments in response to the Food and Drug Administration's (FDA) request for comments regarding emergency eyewash ("EE") products. WLF understands that FDA seeks information to assist it in establishing final marketing requirements for EE products as part of the OTC ophthalmic drug product monograph (the "Monograph"). *See* 21 C.F.R. Part 349.

In connection with FDA's efforts to update the Monograph, WLF respectfully suggests that FDA should re-examine basic classification decisions for EE products and recognize the possibility that some EE products should be classified as devices. The Monograph, developed three decades ago, was based on the untested assumption that solutions intended for washing, bathing, or flushing the eye should be classified as drugs. Much has changed in the FDA regulatory world in ensuing decades, including the definitions of what constitutes a "drug" and "device." In particular, FDA in 2002 established the Office of Combination Products (OCP) to

assist with the assignment of new products to one of FDA's medical product centers—the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), or the Center for Devices and Radiological Health (CDRH). When there is doubt regarding which center should take the lead in regulation, a product sponsor is encouraged to file a Request for Designation (RFD) with OCP, which then makes a designation to the appropriate center. *See* 21 C.F.R. §§ 3.7 & 3.8.

Both drugs and devices are defined as including products "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 U.S.C. §§ 321(g) & (h). The principal difference between the two is that a product does not qualify as a "device" if it "achieve[s] its primary intended purposes through chemical action within or on the body of man or other animals." *Id*. § 321(h). If it does *not* achieve its primary intended purposes in that manner, then it generally is classified as a "device."

To WLF's knowledge, FDA has never undertaken a "primary intended purposes" analysis of ophthalmic products in general, or of EE products in particular. WLF respectfully suggests that FDA's efforts to update the Monograph provide the agency with an appropriate opportunity to engage in such an analysis. WLF notes that at least some EE products achieve at least some of their intended purposes through physical action, not chemical action. Accordingly, WLF requests that any revisions of the Monograph take into account the possibility that some EE products are properly classified as devices, not drugs.

I. *Interests of WLF*

The Washington Legal Foundation is a public interest law firm and policy center with supporters in all 50 States. WLF regularly appears before federal and state courts and administrative agencies to promote economic liberty, free enterprise, a limited and accountable government, and the rule of law. It devotes a substantial portion of its resources to defending the rights of individuals and businesses to go about their affairs without undue interference from government regulators. Among WLF's supporters are doctors and patients who desire to advance health care by ensuring that innovative and safe medical products reach the market without undue delay. WLF regularly litigates in support of patients who seek expedited access to life-saving medical products. *See, e.g., Abigail Alliance for Better Access to Investigational Drugs. v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 552 U.S. 1159 (2008). WLF has opposed FDA's recent efforts to restrict the definition of a "device," an effort that may force the reclassification of numerous medical products from "device" to "drug" status and interfere with the ability of patients to obtain access to the latest advances in medical technology. *See, e.g.*, WLF Comments in response to FDA's Draft Guidance on Classification of Products as Drugs and Devices, Docket No. FDA-2011-D-0429 (comments filed September 19, 2011). WLF understands that FDA, in response to a recent adverse federal court decision, has announced plans to issue a new draft guidance. *See Prevor v. Food and Drug Administration*, 895 F. Supp. 2d 90 (D.D.C. 2012).

II. *FDA's Statutory Authority*

Congress adopted the Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C.

§§ 301 *et seq*., to regulate the sale and distribution of drugs and medical devices to the public. The FDCA defines a "device" as a product "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals," or "intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(h)(2) & (3). A product with those characteristics also qualifies as a "drug." 21 U.S.C. § 321(g). Under the FDCA, the principal distinguishing feature between a "device" and a "drug" is set forth in 21 U.S.C. § 321(h)(3); a product qualifies as a device only if it also:

> [D]oes not achieve its primary intended purposes through chemical action within or on the body of man or other animals and . . . is not dependent on being metabolized for the achievement of its primary intended purposes.

A product that meets all the requirements of § 321(h)—including § 321(h)(3)'s "primary intended purposes" requirement—is regulated as a "device," even though it may also qualify as a "drug" under § 321(g). If it does not meet the "primary intended purposes" requirement, it is regulated as a "drug."

III. FDA's Regulation of Ophthalmic Products

FDA has been regulating ophthalmic products as "drugs" since well before passage of the Medical Device Amendments of 1976 gave FDA authority to regulate medical devices. In particular, in 1964 FDA issued a statement of policy requiring that all liquid preparations offered or intended for ophthalmic use be sterile. *See* 21 C.F.R. § 200.50.

In 1983, FDA issued the Monograph in draft form; it was adopted in final form in 1988. *See* 21 C.F.R. Part 349. The Monograph sets forth standards for over-the-counter ophthalmic

"drug products." It states that such products are "generally recognized as safe and effective" and are not deemed misbranded if they meet the standards set forth in the Monograph as well as the general conditions set forth in 21 C.F.R. § 330.1. An unstated assumption of the Monograph is that all such over-the-counter ophthalmic products should be classified as drugs, not devices.

The Monograph does not include conditions of use for EE products because no safety or efficacy data or other information on these products were submitted to FDA during the 1983-88 rulemaking process. In response to industry requests for clarification of the regulatory status of EE products, in 2003 FDA proposed to amend the Monograph to include a section on EE products. However, no amendment was ever made, and the status of EE products remains in limbo. In the interim, FDA has stated that it will exercise its enforcement discretion to permit the continued marketing of over-the-counter EE products, even in the absence of an approved NDA, provided that certain conditions are met. *See, e.g.*, 78 Fed. Reg. 57397, 58398 (Sept. 18, 2013).

IV. The Need to Re-Examine Product Classification

As noted, FDA began regulating ophthalmic products as drugs in an era when they clearly met the statutory definition of a "drug" and the Medical Devices Amendment had not yet been adopted. The Monograph was drafted in the 1980s before Congress and FDA had established a formal process for differentiating drugs from devices. Now that those procedures are in place—the OCP was established in 2002 at the behest of Congress and has established procedures for determining product classification—it makes little sense for FDA to continue with its untested assumption that all ophthalmic products (and in particular, all EE products) are

drugs.

In order to determine whether a product is a drug or a device, it is first necessary to determine the product's "primary intended purposes." For most EE products, the "primary" intended purpose is to flush or irrigate the eye to reduce chances of severe injury caused by acid, alkali, or particulate contamination. Once the "primary" intended purposes are established, one must determine whether those purposes are achieved "through chemical action within or on the body of man." 21 U.S.C. § 321(h)(3). Flushing and irrigating the eye generally involves a physical action, not a chemical action, thus suggesting a device classification.

EE products consist primarily of water. Besides water, desirable ingredients are those that make the flushing fluid hypertonic—that is, fluids with a higher osmotic pressure than surrounding fluids. A hypertonic fluid will push the offending chemicals out of the cells of the eye. That effect is also physical in nature, and is not a chemical action—again suggesting a device classification.

It is possible that some EE products have a "primary" intended purpose that is achieved through chemical action, in which case they should be classified as drugs. WLF is not in a position to offer classification guidance for any specific product. Rather, WLF's purpose in filing these comments is to alert FDA to the classification issue and to ensure that any revision to the Monograph takes into account that the possibility that some EE products should properly be classified as "devices," not "drugs."

CONCLUSION

The Washington Legal Foundation respectfully requests that any revision of the Monograph take into account the possibility that some EE products should properly be classified as devices, not drugs, and provide standards for undertaking that classification.

Sincerely,

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