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April 18, 2007

Division of Dockets Management,
Food and Drug Administration,
Department of Health and Human Services,
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852.

CITIZEN PETITION

The undersigned submits this petition under 21 C.F.R. 10.25(a) and 10.30, and SEC. 501 and 502 of the Food Drug and Cosmetic Act (FD&C Act) to request the Commissioner of Food and Drugs to take prompt enforcement actions due to the clearly defined public health risk of Toxic Anterior Segment Syndrome (TASS) and secure the removal of illegally marketed unapproved ophthalmic Balanced Salt Solution drugs from the market, as well as the improperly classified medical devices and Over the Counter (OTC) irrigating solutions being sold as ophthalmic Balanced Salt Solutions.

A. ACTION REQUESTED

According to the publicly available report from the American Academy of Ophthalmology (AAO) (see Appendix 1), the report from the American Society of Cataract and Refractive Surgery (ASCRS) (see Appendix 2) and the Agency's February 13, 2006 press release which details the dangerous levels of endotoxin in these illegally marketed drugs (see Appendix 3) there is a serious public health risk of Toxic Anterior Segment Syndrome (TASS) that can be associated with illegally marketed unapproved drugs (see Appendix 4).

The undersigned is seeking expedited enforcement action by the Commissioner of the FDA that will safeguard public health and permanently remove any illegally marketed unapproved ophthalmic Balanced Salt Solution drugs from the market, as well as the improperly classified

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medical devices and Over the Counter (OTC) irrigating solutions being sold as ophthalmic Balanced Salt Solutions, until such time as they are the subject of an approved New Drug Application or Abbreviated New Drug Application.

Due to the unresolved serious public health risk, the undersigned requests that the Commissioner take expeditious action in this case, well in advance of the normal statutory timeframes associated with the Citizen Petition process.

B. STATEMENT OF GROUNDS

After repeated requests from the Agency, Alcon submitted an NDA on June 5, 1996 under SEC 505(b)(2) for Balanced Salt Solution (BSS), an intraocular irrigating solution. The primary purpose of an intraocular irrigating solution is to maintain both the anatomic and physiologic integrity of intraocular tissues. Many physiologic studies performed on the corneal endothelium have confirmed that a solution with a chemical composition similar to aqueous and vitreous humor provides the best protection for intraocular tissues. Approval for NDA 20-742 was granted on December 10, 1997. Alcon was fully aware that the same request had gone out to the other manufacturers of BSS and that a Federal Register notice was expected to issue calling for NDAs or ANDAs by all manufacturers. Alcon took the initiative to set the standard and filed the first NDA, leaving other manufacturers the option to meet the essential equivalence standards of an ANDA. The obligations under an NDA are additionally burdensome with respect to product maintenance compared to competitor's product marketed without an approved NDA, or ANDA.

In accordance SEC 501 and 502 of the (FD&C Act) and with the Agency's *Guidance for FDA Staff and Industry Marketed Unapproved Drugs – Compliance Policy Guide, June 2006*, and due to the clearly defined public health risk, Alcon requests that expedited enforcement action be taken to remove any illegally marketed unapproved ophthalmic Balanced Salt Solution drugs from the market, as well as the improperly classified medical devices and Over the Counter (OTC) irrigating solutions being sold as ophthalmic Balanced Salt Solutions. In addition, these products should not be allowed to return to the market until they are the subject of an approved New Drug Application or Abbreviated New Drug Application. The Agency's Compliance Policy Guide points out that current Agency thinking is "When a

company obtains approval to market a product that other companies are marketing without approval, FDA normally intends to allow a grace period of roughly 1 year from the date of approval of the product before it will initiate enforcement action (e.g., seizure or injunction) against marketed unapproved products of the same type.” Clearly it is one year past the December 10, 1997 approval of NDA 20-742.

Examples of illegally marketed unapproved BSS drugs include:

- AMO Endosol (see Appendix 5)
- Baxter’s Balanced Salt Solution where their NDC code references Alcon’s NDA (see Appendix 6)
- Cytosol Ophthalmics Balanced Salt Solution (see Appendix 7)

Due to serious public health concerns such as TASS, or other ophthalmic complications that can occur from an adulterated BSS product, it is Alcon’s expectation that the Agency will remove all such product from the market.

The Agency’s Compliance Policy Guide is also quite clear in the case of serious public health concerns and states:

- The top enforcement priority: “Drugs with potential safety risks. Removing potentially unsafe drugs protects the public from direct and indirect health threats.”
- “the effects on the public health of proceeding immediately to remove the illegal products from the market (including whether the product is medically necessary and, if so, the ability of legally marketed products to meet the needs of patients taking the drug)”.

Alcon hereby notifies the Agency that we are prepared to meet the needs of the United States ophthalmic surgery community and continue to supply BSS (Balanced Salt Solution) NDA 20-742 and BSS PLUS NDA 18-469 and assures the Agency that there is not a concern for drug shortages.

Again, due to the unresolved serious public health risk, the undersigned requests that the Commissioner take expeditious action in this case, well in advance of the normal statutory timeframes associated with the Citizen Petition process.

C. ENVIRONMENTAL IMPACT STATEMENT

A claim for categorical exclusion of the requirement for submission of an environmental assessment is made pursuant to 21 CFR 25.31.

D. CERTIFICATION

The undersigned certifies that, to the best of his knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



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