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Statement of Serono, Inc.

Before the

Task Force on Drug Importation

April 5, 2004

Serono appreciates the opportunity to provide comments to the Task Force on Drug Importation. Serono is a global biotechnology leader. In addition to being the world leader in reproductive health, Serono has strong market positions in neurology, metabolism and growth. The Company's research programs are focused on growing these businesses and on establishing new therapeutic areas.

Introduction

Serono believes that changes to regulations governing drug importation or reimportation have a significant potential to increase safety risks for patients and consumers due to increased drug diversion and entry of counterfeit drugs to the U.S. market. Any perceived or potential cost savings for U.S. consumers achieved through drug importation would be far outweighed by the potential costs to patient safety, product integrity and confidence in the U.S. drug distribution system.

Safeguarding Our Drug Products from Diversion and Counterfeiting

During 2000, Serono detected what was confirmed to be a counterfeited version of one of its products, Serostim®. Serostim® [somatropin (rDNA origin) for injection] is a recombinant human growth hormone indicated for the treatment of HIV patients with wasting or cachexia and is administered by subcutaneous injection.

As part of its usual product support services, Serono has a quality assurance group that, among other responsibilities, receives, processes and initiates investigation of any technical complaints regarding Serono products. It is this group that in late 2000, received the first calls that alerted the company to the potential existence of counterfeit product.

Callers reported that the vials of diluent (sterile water for injection that is mixed with the active drug product just prior to administration) appeared to be

under filled. A few callers also reported some stinging or burning at the injection site for one particular lot number. Per our usual procedures, replacement product was provided to patients through their pharmacies and we asked that the "suspect" product be sent to us. Upon receipt and visual inspection of this material, it was determined that the questionable product was not Serono's product at all but rather a counterfeit product labeled and packaged to appear as Serostim®. This counterfeit material made its way into the U.S. retail drug distribution system.

Serono immediately notified the FDA's Office of Criminal Investigations regarding the counterfeit material and numerous discussions with various offices within FDA at the local, regional and federal levels followed. Serono also, on its own initiative, alerted pharmacists and drug wholesalers to the counterfeit material and recommended that they examine Serostim® prior to dispensing to see if it had a particular lot number and expiration date or other identifying features of the counterfeit material. We also informed physicians prescribing Serostim® and AIDS service organizations about the existence of the counterfeit materials, sent out a press release and posted information about the counterfeit material on our company website and on the FDA website to spread the word further. Because individual patient information is not available to Serono, the company could not conduct any outreach to patients directly.

Serono Established a Serostim® Secured Distribution Program

In total, Serono has experienced three discoveries of counterfeit Serostim® material. The unusual circumstance with this product prompted the company to design a program that would secure the integrity of Serostim® without jeopardizing patient access. The system is designed to tighten control of distribution, to detect the entry into our distribution system of counterfeit or diverted product and to allow for the tracking and tracing of each individual box.

Serono undertook an intensive process of designing what is known today as the Serostim® Secured Distribution Program. Changes were made within manufacturing in order to add bar-coding and a unique numbering system for each box of Serostim®. Specifications for track and trace capabilities were developed and a technology partner was identified to implement this system. Finally, a network of contracted pharmacies was needed to meet the program criteria. Throughout the planning process key stakeholders were informed about the program that was being developed—from state boards of pharmacy to AIDS service organizations to wholesalers, pharmacies and prescribing physicians.

In October 2002, following several months of research and planning, Serono implemented the innovative Serostim® Secured Distribution Program to track Serostim® through the distribution chain and to increase assurance that consumers who were prescribed Serostim® received the genuine FDA-approved

product. With its tracking of each prescription size package of Serostim®, the program provides deterrence and valuable intelligence for use in prosecution of those individuals who may attempt to misuse or misdirect the product. Serono has responded to requests from law enforcement to utilize the tracking and tracing capabilities to provide information for use in ongoing investigations.

Illicit Sale of Drug Products Online

Serono also periodically monitors the Internet for websites mentioning Serono products. From time to time, we have identified illicit Internet activity related to our drugs where online pharmacies are not appropriately licensed and are not in compliance with state and federal pharmacy laws. Various of these internet pharmacies claim to offer Serono products yet they are outside of our distribution system and often these products are not what they purport to be. In such cases, we have issued cease and desist orders in relation to our products and alerted the FDA Office of Criminal Investigations as to our concerns about particular websites.

In one example of illicit Internet activity, in 2003 Serono discovered that Serono products were being offered for sale on eBay. It is not possible to confirm whether products are genuine based on the posted information. Serono contacted eBay's General Counsel to request the immediate removal of the posting; eBay removed the listing for violation of their policy prohibiting the sale of prescription drugs and ultimately agreed to use technology filters to prevent further postings of Serono products.

Risk of Liberalized Importation

Serono does everything within its reasonable span of control to assure patient safety and product integrity and these additional steps have been taken at our own initiative. However, no such programs can be considered "fool-proof" therefore, Serono is taking one more step by expressing its opposition to the liberalizing of drug importation laws.

Serono believes that loosening restrictions on drug importation from foreign sources would hinder our ability to carry out track and trace programs such as the one that we now have in place for Serostim®. Our program is focused on safety and security within the U.S. Opening the borders to importation of products intended for distribution elsewhere would render the program ineffective. Changing current practice also changes the dynamics of drug distribution and raises new incentives for illegal activities.

The American public relies on the U.S. Food and Drug Administration (FDA) to ensure that drug products in the United States are proven to be both safe and effective. The subsequent maintenance of these drugs, monitoring and post-

marketing reporting, as well as security of the distribution/supply chain are also of critical importance.

FDA standards for demonstration of safety and effectiveness are rigorous with numerous regulations covering the vast aspects of drug development and registration, including the conduct of clinical trials in humans, processes and facilities for product manufacture and testing, product storage and therapeutic labeling claims, and instructions to physicians and patients, which provide important information on the risks, benefits and use of any particular drug. Such standards for product approval and maintenance differ from country to country as do the mechanisms for distribution of product through the respective supply chains.

Although attempts are underway to harmonize certain technical components of product registrations through the International Conference on Harmonization, the reality is that there is no common standard for judging the safety and effectiveness of products on a worldwide basis. In fact it is not uncommon for major health authorities to disagree on the approvability and/or labeling of drugs. We urge Congress and the Administration to maintain current policy and take steps to increase surveillance of commerce in prescription drugs originating from foreign sources.

We commend the Task Force for its efforts on this very important public policy issue and on behalf of Serono, I would like to thank the Task Force for the opportunity to provide these comments, which we hope will be helpful in its deliberations.

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