DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-983

Meridian Medical Technologies, Inc.
Attention: Thomas G. Freund
Director, Regulatory Affairs
1945 Craig Road
St. Louis, MO 63146

Dear Mr. Freund:

Please refer to your New Drug Application (NDA), dated March 24, 2006, received March 28, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Duodote (atropine and pralidoxime chloride injection) Auto-Injector.

We acknowledge receipt of your additional submissions dated September 29, 2005, February 2, 2006, February 15, 2006, March 14, 2006, May 4, 2006, May 15, 2006, May 23, 2006, June 21, 2006, July 20, 2006, and July 28, 2006.

This new drug application provides for the use of Duodote for the treatment of poisoning by organophosphorous nerve agents as well as organophosphorous insecticides. The Duodote Auto-Injector should be administered by emergency medical services personnel who have had adequate training in the recognition and treatment of nerve agent or insecticide intoxication.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor revisions listed below.

1. In the Instruction Sheet for Emergency Medical Personnel, graphics should be enhanced when the final artwork is generated prior to printing the final labeling. The "Caregiver Aid" graphics will be renamed "Emergency Personnel Aid". In Figure 6, separate illustrations will be provided for "needle visible" and "needle not visible".

2. We remind you that regulations require the label for a parenteral product to include the quantity or proportion of all inactive ingredients, except that ingredients added to adjust the pH or to make the drug isotonic may be declared by name and a statement of their effect; and if the vehicle is water for injection it need not be named. Therefore, the Duodote carton label should be revised to meet this requirement.

3. On the Duodote container label, "PROTECT" should be on the same line as "FROM LIGHT".

4. We remind you that Duodote should be substituted where ever "TRADENAME" appears in labeling.

In addition, we note that the "Instruction Sheet for Emergency Medical Services Personnel", which is at the end of the package insert, will be reprinted as a separate document to be included in the Duodote product carton.

The final printed labeling (FPL) must be identical to, except for including the revisions listed above, the enclosed labeling (text for the package insert, text for the instruction sheet, immediate container and carton labels). These revisions are terms of the NDA approval. Marketing the product before making the revisions, as stated, in the product's labeling may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-983**." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

Pediatric Study Commitments

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies for ages birth to less than 17 years until September 30, 2009.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the treatment of poisoning by organophosphorous nerve agents as well as organophosphorous insecticides in pediatric patients ages birth to less than 17 years.

   Final Report Submission: September 30, 2009

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated "**Required Pediatric Study Commitments**".

Promotional Material

Submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Jacqueline H. Ware, Pharm.D., Senior Regulatory Project Manager at (301) 796-2250.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz

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