**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-106/S-028

Meridian Medical Technologies, Inc
Attention: Gerald Wannarka, Ph.D.
2550 Hermelin Drive
St. Louis, MO 63144-2591

Dear Dr. Wannarka:

Please refer to your supplemental new drug application dated December 23, 2002 and received on December 27, 2002; submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AtroPen® (atropine) Injection.

We also acknowledge receipt of the following amendments and correspondence:

| | |
|---|---|
| April 7, 2003 | June 12, 2003 |
| April 8, 2003 | June 13, 2003 |

This supplemental new drug application provides for use of the AtroPen® Autoinjector in pediatric populations and includes information to support two lower strength AtroPen® autoinjectors (0.5 mg and 1 mg) and a revised package insert for use in both adult and pediatric populations.

We completed our review of this application, as amended and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon attached labeling text.

The final printed labeling (FPL) must be identical to the agreed upon attached draft package insert and "Self-Aid and Caregiver Aid Directions for Use". We ask that you also review and update the carton/container labeling contained within the application, if necessary, to reflect changes that have been incorporated into the "Self-Aid and Caregiver Aid Directions for Use" labeling.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-106/S-028." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment in your submission dated June 12, 2003. This commitment is listed below.

> We note your commitment to(b)(4)----------auto-injector product for the treatment of organophosphorous insecticide and nerve agent poisoning in children 6 months of age and under. You have indicated that this auto-injector will be

functionally identical to the EpiPen® Jr product that your firm currently manufactures and will deliver an intramuscular dose of (b)(4)----atropine in a volume of 0.3 mL. We also note your commitment to submit a supplemental application for this additional strength within 9 months of the date of this letter.

Submit chemistry, manufacturing, and controls protocols and all study final reports, as appropriate, to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of this commitment in your annual report to this NDA. The status summary should include expected summary completion and submission dates, any changes in plans since the last annual report. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "Postmarketing Study Correspondence."

In addition, 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 inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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, please call Mr. Robbin Nighswander MS, Supervisory Regulatory Health Project Manager, at (301) 594-2850.

Sincerely,

*{See appended electronic signature page}*

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

Enclosures (2)

---

**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
6/19/03 03:39:56 PM