DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021983/S-023

SUPPLEMENT APPROVAL

Meridian Medical Technologies, Inc.
Attention: Pamela Uetrecht
Manager, Regulatory Affairs
1945 Craig Road
St. Louis, MO 63146

Dear Ms. Uetrecht:

Please refer to your Supplemental New Drug Application (sNDA) dated and received December 7, 2016, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DuoDote (atropine and pralidoxime chloride injection) autoinjector.

This Prior Approval supplement provides for the expansion of the approved DuoDote indication to include pediatric patients weighing greater than 41 kg. This supplement also provides for the conversion of the DuoDote Prescribing Information (PI) to comply with the final rules, "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products," published January 24, 2006 [also known as the Physician Labeling Rule (PLR)], and "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling" published in June 30, 2015 [also known as the Pregnancy and Lactation Labeling Rule (PLLR)].

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the instruction sheet for healthcare providers, and text for the instructions for use), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the carton and immediate-container labels submitted on September 29, 2017, except with the revision listed below, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 021983/S-023**." Approval of this submission by FDA is not required before the labeling is used.

1. The brown labeling element on the autoinjector, carton, and pouch labels will be revised by changing [redacted] (b) (4) to "For adults and pediatric patients weighing 41 kg + or 90 lb +".

We note that, in your October 4, 2017, amendment to this supplement, you have agreed with this change and have committed to submitting the revised labeling pieces as final carton and container labels to NDA 021983 no later than two weeks after S-023 approval.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to supplement (S-023), you are exempt from this requirement.

In addition, we refer to the following postmarketing requirement listed in our September 28, 2006, approval letter for NDA 021983:

1300-1: 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.

We acknowledge that this supplement partially addresses PREA PMR 1300-1, for pediatric patients weighing greater than 41 kg (generally 10 years of age and older), but it does not address pediatric patients ages birth to less than 10 years. Therefore, your pediatric assessment required under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c) has not yet been fulfilled.

SUPPLEMENT SUPERSEDED

The conversion of the DuoDote PI to PLR, as part of NDA 021983/S-023, submitted on December 7, 2016, addresses deficiencies described in the Agency's December 11, 2013, Complete Response (CR) letter for NDA 021983/S-009, submitted on October 14, 2009. Because supplemental application S-023 supersedes supplemental application S-009, we will not review S-009 any further. However, we will retain S-009 in our files.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For

more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

REPORTING REQUIREMENTS

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 Harold Sano, PharmD, MBA, Regulatory Project Manager, at (301) 796-2429.

Sincerely,

{See appended electronic signature page}

Eric Bastings, MD
Deputy Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

ERIC P BASTINGS
10/06/2017