DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022266/S-001 **SUPPLEMENT APPROVAL**

Meda Pharmaceuticals, Inc.
265 Davidson Avenue, Suite 300
Somerset, NJ 08873-4120

Attention: Richard Fosko, R.Ph., M.P.H.
Director, Regulatory Affairs

Dear Mr. Fosko:

Please refer to your supplemental new drug application (sNDA) dated and received October 30, 2009 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Onsolis (fentanyl buccal soluble film).

We acknowledge receipt of your submissions dated January 15, 2009, and April 23, and April 26, 2010, and your risk evaluation and mitigation strategy (REMS) assessment dated January 15, 2010.

This "Prior Approval" supplemental new drug application provides for product labeling revised to reflect the transfer of ownership of NDA 022266, which was effective on July 28, 2009, and proposed modifications to the approved REMS as described below.

We have 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 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, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert and Medication Guide.). 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 for this NDA, including pending "Changes Being Effected" (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.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Onsolis was originally approved on July 16, 2009, and consists of a Medication Guide, elements to assure safe use, and a timetable for the submission of assessments of the REMS. The proposed modifications to the REMS and REMS materials in this supplement include:

1. Change in the applicant's name, address and contact information to reflect the new NDA ownership in the Medication Guide, REMS materials, and REMS document.
2. A new form, "Patient Continuation Form", was added to the prescriber enrollment materials.
3. The "Healthcare Professional Program Overview" form was modified.
4. The "Patient Enrollment" form was modified.
5. The Call Center templates FF05, FF09, and FF010 were modified.
6. The "Information for Pharmacist" webpage was updated.
7. The Focus™ Program prescription process has been condensed.

Your modified REMS, submitted on October 30, 2009, and appended to this letter, is approved. The REMS consists of a Medication Guide, elements to assure safe use, and a timetable for the submission of assessments of the REMS. The REMS assessment plan will remain the same as that approved on July 16, 2009.

The following items from your REMS approved on July 16, 2009, were not modified in this supplement but are attached to this letter for completeness:

- Dear Prescriber Letter
- Printed Educational Materials
- Pharmacy Enrollment Form
- Dear Pharmacist Letter
- Patient Program Overview
- Wholesaler/Distributor Enrollment Form

Prominently identify submissions containing REMS-related submissions with the following wording in bold capital letters at the top of the first page of the submission:

NDA 022266
REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 022266
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE) FOR NDA 22266
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

PROMOTIONAL MATERIALS

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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 Kimberly Compton, Senior Regulatory Project Manager, at (301) 796-1191 or at Kimberly.compton@fda.hhs.gov.

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Sincerely,

{See appended electronic signature page}

Larissa Lapteva, M.D., M.H.S.
Deputy Director for Safety
Division of Anesthesia and Analgesia Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:

Package Insert
Medication Guide
REMS

- Healthcare Professional Program Overview
- Prescriber Enrollment Form (including Prescriber Knowledge Assessment)
- Website Educational Materials
- Patient Enrollment Form (including HIPPA Authorization)
- Dear Prescriber Letter
- Printed Educational Materials
- Pharmacy Enrollment Form
- Dear Pharmacist Letter
- Patient Program Overview
- Wholesaler/Distributor Enrollment Form

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22266	SUPPL-1	MEDA PHARMACEUTICALS INC	FENTANYL CITRATE / BEMA FENTANYL

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

/s/

LARISSA LAPTEVA
07/01/2010