DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

TO *(Office/Division)*: Office of Safety and Epidemiology
Attn: Cheryl Wiseman

FROM *(Name, Office/Division, and Phone Number of Requestor)*: Division of Anesthesia, Analgesia and Rhuematology Products; Dr. Bob Rappaport, 6-2280

DATE	IND NO.	NDA NO.	TYPE OF DOCUMENT	DATE OF DOCUMENT
December 17, 2007		22-266	NDA	October 28, 2007

NAME OF DRUG	PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE
BEMA fentanyl			March 28, 2008

NAME OF FIRM: BioDelivery Sciences International

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE / ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE-NDA MEETING
- ☐ END-OF-PHASE 2a MEETING
- ☐ END-OF-PHASE 2 MEETING
- ☐ RESUBMISSION
- ☐ SAFETY / EFFICACY
- ☐ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☒ OTHER *(SPECIFY BELOW)*:

COMMENTS / SPECIAL INSTRUCTIONS: Please review and provide comment on the RMP in this NDA.

This NDA is located in the EDR.
If you have any questions, please contact Kim Compton at 6-1191 or Ellen Fields, Medical Officer, at 6-1209.

SIGNATURE OF REQUESTOR
Kimberly Compton 12/17/07

METHOD OF DELIVERY (Check one)
☒ DFS ☐ EMAIL ☐ MAIL ☐ HAND

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/s/

Lisa Malandro
12/19/2007 09:59:14 AM
Lisa Malandro for Kim Compton

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

TO *(Office/Division)*: Controlled Substances Staff;
Attn: Corinne Moody

FROM *(Name, Office/Division, and Phone Number of Requestor)*: Division of Anesthesia, Analgesia and Rhuematology Products; Dr. Bob Rappaport, 6-2280

DATE	IND NO.	NDA NO.	TYPE OF DOCUMENT	DATE OF DOCUMENT
December 17, 2007		22-266	NDA	October 28, 2007

NAME OF DRUG	PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE
BEMA fentanyl			March 24, 2008

NAME OF FIRM: BioDelivery Sciences International

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE / ADDITION
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- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☒ OTHER *(SPECIFY BELOW)*:

COMMENTS / SPECIAL INSTRUCTIONS: Please review and provide comment on the RMP and CSS-related aspects of this NDA. This NDA is located entirely in the EDR.

If you have any questions, please contact Kim Compton, 301-796-1191 or Ellen Fields (medical officer) at 301-796-1209.

SIGNATURE OF REQUESTOR
Kimberly Compton/12/17/07

METHOD OF DELIVERY (Check one)
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/s/

Lisa Malandro
12/19/2007 09:57:50 AM
Lisa Malandro for Kim Compton

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 22-266

NDA ACKNOWLEDGMENT

BioDelivery Sciences Internatonal, Inc.
801 Corporate Center Drive
Suite 210
Raleigh, NC 27607

Attention: David T. Wright, PhD, RAC
Director, Regulatory Affairs

Dear Dr. Wright:

We have received your new drug application (NDA) submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Tradename (fentanyl bioerodible mucoadhesive [redacted] oral transmucosal 200, 400, 600, 800, and 1200 mcg b(4)

Date of Application: October 31, 2007

Date of Receipt: October 31, 2007

Our Reference Number: NDA 22-266

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on December 30, 2007 in accordance with 21 CFR 314.101(a).

If you have not already done so, promptly submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html. Failure to submit the content of labeling in SPL format may result in a refusal-to-file action under 21 CFR 314.101(d)(3). The content of labeling must be in the Prescribing Information (physician labeling rule) format.

The NDA number provided above be cited at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anesthesia, Analgesia and Rheumatology Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, please see http:www.fda.gov/cder/ddms/binders.htm.

If you have any questions, call me at (301) 796-1191.

Sincerely,

{See appended electronic signature page}

Kimberly Compton, RPh
Regulatory Project Manager
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

Sara Stradley
11/9/2007 12:54:37 PM
for Kim Compton