

How to respond directly to the FDA to urge them to reconsider their decision

Directions:

- The letters should be addressed to Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER), and include a cc to FDA Commissioner Hamburg
- The letters must list the NDA number so they can be filed appropriately
- Best way to send a letter is as a PDF attachment to an e-mail
- If possible, it is also recommended that a hard copy be sent via FedEx, which means the letter will be signed for and someone in CDER will actually read the letter.

Template Format for Letter

(Letterhead)

(Date)

Janet Woodcock, MD
Director, Center for Drug Evaluation and Research (CDER)
Food and Drug Administration
White Oak Complex
Building 51; Room 6133
10903 New Hampshire Avenue
Silver Spring, MD 20993
janet.woodcock@fda.hhs.gov
301-796-5400

Re: NDA 204442 for Probuphine for Subdermal Use

Dear Dr. Woodcock:

(Body of the letter)

After Signature:

Full Name
Title
Address
E-mail address

CC:

**Dr. Margaret Hamburg, Commissioner
Food and Drug Administration
White Oak Building One
10903 New Hampshire Avenue; Room 2217
Silver Spring, MD 20993
margaret.hamburg@fda.hhs.gov**