NEW YORK STATE DEPARTMENT OF HEALTH
MEDICAID MANDATORY GENERIC CLINICAL EXEMPTION REQUEST

Instructions: Sections 1 and 2 must be completed in full. Complete all applicable parts of Section 3 (page 2). Request must be signed and dated to be considered. Return completed request to:

Mandatory Generics
New York State Department of Health
Office of Health Insurance Programs
Corning Tower (OCP 720)
Albany, NY 12237

SECTION 1. REQUESTOR INFORMATION

REQUESTOR/CONTACT PERSON_____
TITLE _____
COMPANY/ORGANIZATION_____
ADDRESS_____
CITY_____ STATE_____ ZIP CODE_____
PHONE _____ FAX _____
E-MAIL _____

CHECK ONE
☐ Manufacturer/Representative
☐ Consumer Advocacy Group
☐ Practitioner
☐ Other _____

For State Use Only
Log# _____
Date Received _____
Recommendation Date _____
☐ Exemption ☐ No Exemption

SECTION 2. PRODUCT TO BE EXEMPTED (The FDA website (www.fda.gov) can be used as a resource for the following information.)

1. Name of BRAND, multi-source product_____
2. Is there currently a GENERIC version with a FDA approved "A" bio-equivalence rating?
   ___ YES ___ NO IF NO, STOP HERE
3. GENERIC product name _____
4. FDA approval date for GENERIC mm/dd/yy _____
5. Date GENERIC made available in US market mm/dd/yy _____
6. Patent expiration date for BRAND mm/dd/yy _____
7. FDA "Orange Book" therapeutic equivalence code _____
8. FDA approved indications:
   a. _____
   b. _____
   c. _____

SECTION 3. JUSTIFICATION FOR EXEMPTION

1. Please provide a copy of any valid, evidence based clinical studies that support the following:

A. BRAND provides a superior outcome/result over available GENERIC agents.

_____

_____

B. Unacceptable variability exists between lots of GENERIC agents in question as compared to BRAND.

_____

_____

C. Other clinically significant concerns attributable to GENERIC formulation.

_____

_____

2. Has FDA been notified of untoward outcomes of the GENERIC, or indications of less than effective treatment outcomes based on use of GENERIC? If so, how (e.g., Medwatch, written correspondence)? (Attach copy if available.)

_____

_____

3. Describe significant clinical implications for treatment failure that results from using the GENERIC version of this drug. _____

_____

4. Please provide endorsements made by nationally accredited medical boards or academies in the related clinical field that supports the use of BRAND instead of GENERIC. (Attach copy.)_____

_____

5. Describe any adverse medical outcomes anticipated for specific patient populations which may result from the use of a bioequivalent GENERIC agent. _____

_____

6. Other clinical or financial issues that should be considered._____

_____

I _____ **(print name) certify that I am authorized to submit this request on behalf of the organization identified On This request.**

Signature _____ **Date** _____