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 ______________________________________ STATE _________ ZIP CODE __________
PHONE ___________________________ FAX __________________________________
E-MAIL __________________________________________________________

CHECK ONE For State Use Only
☐ Manufacturer/Representative Log# ____________________________
☐ Consumer Advocacy Group Date Received ______________
☐ Practitioner Recommendation Date ________________________
☐ Other ___________________________________________ ☐ 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. _____________________________________________________________

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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 ___________________