# 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
Bureau of Program Guidance
99 Washington Avenue, Suite 607
Albany, New York 12210

## 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** mo da yr |_|_|_| |_|_|_| |_|_|_| |
| **5. Date GENERIC made available in US market** mo da yr |_|_|_| |_|_|_| |_|_|_| | **6. Patent expiration date for BRAND** mo da yr |_|_|_| |_|_|_| |_|_|_| |

| | |
|---|---|
| **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 <u>significant</u> clinical implications for treatment failure that results from using the GENERIC version of this drug.**

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**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.)**

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

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_____
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_____

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

_____
_____
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_____

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

**Signature** _____ **Date** mo da yr
I_I I_I I_I I_I I_I I_I