# GENERAL CONFORMITY CERTIFICATE

**Pursuant to 15 U.S.C. § 2063(a), the parties identified in boxes 3, 4, and 5 (as applicable) hereby certify, based on a reasonable testing program (and third party testing, as applicable), that the product identified in box 1 complies with the regulations, rules, bans, and/or standards identified in box 2.**

**Issue Date: 7 November 2008**

*1. Specific product covered by this certificate:* **ACTONEL® (risedronate sodium) 5 mg tablet or 30 mg tablet, 30 count bottle.**

*2. Specific regulation(s), rule(s), ban(s), and/or standard(s) for which this product is being certified:*

**Above-referenced product is subject to provisions of the Poison Prevention Packaging Act (PPPA). Manufacturer certifies compliance with 16 CFR 1700.14(a)(10) (prescription drugs) and 16 CFR 1700.15 (poison prevention packaging standards).**

*3. Domestic or foreign manufacturer (as applicable) certifying compliance:*

Name: **Procter & Gamble Pharmaceuticals, Inc.**
Mailing address: **1 Procter & Gamble Plaza, Cincinnati, OH 45202**
Telephone number: **866-607-5535**

*4. Importer certifying compliance (provide this information only if the product is imported):*

Name: **Not applicable**
Mailing address:
Telephone number:

*5. Private labeler certifying compliance (provide this information only if there is a private labeler):*

Name: **Not applicable**
Mailing address:
Telephone number:

*6. Individual maintaining records of the test results upon which this certification is based:*

Name: **Quality Assurance Manager**
Mailing address: **Procter & Gamble Pharmaceuticals, 8700 Mason-Montgomery Road, Mason Ohio, 45040**
Telephone number: **866-607-5535**

*7. Date and place where this product was manufactured:*

**Varies. Each shipping case indicates the place of manufacture, a unique eight-digit finished product code and a unique lot number, which are used together to identify the date of manufacture.**

**Additional detailed information may be obtained by calling 866-607-5535**

*8. Date and place where this product was assessed for compliance with the regulation(s), rule(s), ban(s), and/or standard(s) cited above:*

Date(s) of assessments: **Varies, based on the date a specific product was assessed prior to introduction in the market.**
Address(es) where assessments occurred: **Procter & Gamble Pharmaceuticals, 8700 Mason-Montgomery Road, Mason Ohio, 45040**

Assessments are conducted as part of P&GP's reasonable testing program upon which this certificate is based, which may include but is not necessarily limited to one or more of the following elements: safety surveillance monitoring, packaging qualification, product design rationales, statistical analyses, technical review of literature and pilot studies, and/or other quality assurance activities.

*9. Third party laboratory(ies) that conducted testing upon which this certification is based (provide this information only if this certification is based, in whole or in part, on testing conducted by one or more third party laboratories):*

Name(s): **Varies, based on the date a specific product was assessed prior to introduction in the market.**
Mailing address: **Procter & Gamble Pharmaceuticals, 8700 Mason-Montgomery Road, Mason Ohio, 45040**
Telephone number(s): **866-607-5535**

Assessments are conducted as part of P&GP's reasonable testing program upon which this certificate is based, which may include but is not necessarily limited to one or more of the following elements: safety surveillance monitoring, packaging qualification, product design rationales, statistical analyses, technical review of literature and pilot studies, and/or other quality assurance activities.