

GENERAL CONFORMITY CERTIFICATION

This General Conformity Certification is being provided pursuant to section 14(a) of the Consumer Product Safety Act as amended, 15 U.S.C. 2063(a), and section 102(a)(1) of the Consumer Product Safety Improvement Act of 2017 for products contained in child-resistant packaging in accordance with the Poison Prevention Packaging Act and implementing regulations. See 16 C.F.R. § 1700.14.

| Identification of the product covered by the certificate. Regulation(s), rule(s), ban(s), and/or standard(s) to which this product is being certified: | Tarceva® (erlotinib) tablets: 25 mg/tablet, 30 tablets per bottle (NDC 50242-062-01) 100 mg/tablet, 30 tablets per bottle (NDC 50242-063-01) 150 mg/tablet, 30 tablets per bottle (NDC 50242-064-01) 16 C.F.R. § 1700.14(a)(10) |
|--|--|
| Identification of the U.S. importer or | Astellas US Technologies, Inc. |
| domestic manufacturer certifying | 1 Astellas Way |
| compliance of the product: | Northbrook, IL 60025 |
| | Phone number: 224-205-8800 |
| Individual maintaining test records | Astellas US Technologies, Inc. |
| upon which this certification is | 1 Astellas Way |
| based: | Northbrook, IL 60025 |
| Date and place where this product was manufactured: | Email: <u>medinfo.us@astellas.com</u> Phone number: 224-205-8800 Each manufactured lot is labeled with the National Drug Code (NDC) number and a unique lot number which are used to identify the date and place of manufacture. For additional information, please email <u>medinfo.us@astellas.com</u> . |
| Date and place where this product | 166 Farmington Lane |
| was tested for compliance with the | Lancaster, PA USA 17601 |
| regulation(s), rule(s), ban(s) and/or standard(s) cited above and test | Test Report DPG11-12A dated October 27, 2011 |
| report(s) on which certification is | 166 Farmington Lane |
| based: | Lancaster, PA USA 17601 |
| | Test Report DPG11-12C dated November 11, 2011 |
| Third-party laboratory that | Bird Dog |
| conducted testing upon which this | Marketing Group LLC |
| certification is based: | 166 Farmington Lane |
| | Lancaster, PA USA 17601 |
| DCC attack later | 717-581-6602 |
| Effective date: | October 1, 2018 |