Withdrawal of Approval of Six Abbreviated New Drug Applications

### Application No. | Drug | Applicant
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ANDA 070185 | Fluor-Op (fluoromethalone) Ophthalmic Suspension, 0.1% | Novartis Pharmaceuticals Corp., One Health Plaza, East Hanover, NJ 07936.
ANDA 070858 | Trazodone Hydrochloride Tablets USP, 100 milligrams (mg) | Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 076023 | Hydrocodone Bitartrate and Ibuprofen Tablets, 7.5 mg/200 mg | Teva Pharmaceuticals USA, Inc., 400 Interpace Pkwy., Bldg. A, Parsippany, NJ 07054.
ANDA 078167 | Paclitaxel Injection USP, 6 mg/milliliter | Sandoz, Inc., 100 College Rd. West, Princeton, NJ 08540.
ANDA 088726 | Chlorpropamide Tablets USP, 250 mg | Aurolife Pharma, LLC, 279 Princeton Hightstown Rd., East Windsor, NJ 08520.
ANDA 089852 | Chlorzoxazone Tablets USP, 250 mg | Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of July 11, 2019. Approval of each entire application is withdrawn, including any strengths or products inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on July 11, 2019 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: June 6, 2019.

Lowell J. Schiller,
Principal Associate Commissioner for Policy.