IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PERRIGO ISRAEL PHARMACEUTICALS LTD. 29 Lehi Street B'nei Brak 51200, Israel PERRIGO COMPANY 515 Eastern Avenue Allegan, MI 49010 Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, 200 Independence Avenue, S.W. Washington, DC 20201, Defendant.	)	Case No. _____

COMPLAINT

Plaintiffs, Perrigo Israel Pharmaceuticals Ltd. and Perrigo Company (collectively "Perrigo"), for their complaint against Defendant, the U.S. Food and Drug Administration ("FDA" or the "Agency"), alleges as follows:

NATURE OF ACTION

1. This is an action for declaratory, mandatory injunctive, and other relief arising from FDA's violation of, and failure to take timely action under: the Federal Food, Drug, and Cosmetic Act ("FDC Act"), 21 U.S.C. §§ 301 *et seq.*, as amended by the

Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) ("Hatch-Waxman Amendments"); the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 501 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and 28 U.S.C. §§ 1331, 1361, and 1651. This action seeks redress for FDA's failure to perform its non-discretionary statutory duty to timely update the Agency's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") to add a Therapeutic Equivalence ("TE") rating for Perrigo's FDA-approved Testosterone Gel, 1%, drug product ("Perrigo's Product"), which failure has and continues to cause actual and imminent harm to Perrigo.

2. FDA approved Perrigo's Product more than a year ago, on January 31, 2013, under New Drug Application ("NDA") No. 203098, and based on that approval, had an obligation to timely update the Orange Book with a TE rating for Perrigo's Product. Nevertheless, despite repeated requests by Perrigo to FDA asking the Agency to publish a TE rating for Perrigo's Product, and despite publishing TE ratings for numerous other drugs approved after Perrigo's Product, including at least one drug product submitted pursuant to FDC Act § 505(b)(2) (21 U.S.C. § 355(b)(2), FDA has not fulfilled its statutory obligation as to Perrigo.

3. The FDC Act mandates that FDA publish a list of approved drugs with therapeutic equivalence information. *See* 21 U.S.C. § 355(j)(7)(A)(i)(I)-(III). FDA has elected to fulfill this statutory duty by publishing the Orange Book. The Act further mandates that FDA update the Orange Book, including TE ratings "[e]very thirty days

after the publication." This same section mandates that the Secretary "shall revise the list to include each drug . . . approved . . . during the thirty-day period." *Id.* at § 355(j)(7)(A)(ii).

4. Despite the statutory deadline and Perrigo's requests, FDA has refused to fulfill its statutorily-compelled obligation to publish a TE rating in the Orange Book within the statutory —and any reasonable— time frame. The Agency's failure to take this non-discretionary statutorily-mandated action is in direct contravention of the FDC Act and the APA and has resulted in actual and imminent harm to Perrigo.

PARTIES

5. Plaintiff, Perrigo Israel Pharmaceuticals Ltd., is an Israeli company with its principal place of business at 29 Lehi Street, B'nei Brak 51200, Israel. Plaintiff Perrigo Company, is a Michigan corporation with its principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010. Defendant, FDA, is an agency within the U.S. Department of Health and Human Services ("HHS"), an Executive Department of the United States government. FDA is an "agency" of the government within the meaning of the APA. 21 U.S.C. § 393; 5 U.S.C. § 551(1). FDA maintains offices at 200 Independence Avenue, S.W., Washington, D.C. 20201.

JURISDICTION AND VENUE

6. This action arises under: the FDC Act, 21 U.S.C. §§ 301-399; the APA, 5 U.S.C. §§ 551-559, 701-706; and 28 U.S.C. §§ 1361, and 2201-2202. The declaratory, injunctive, and other relief requested by Plaintiff is authorized by 5 U.S.C. §§ 702, 705

and 706, and 28 U.S.C. §§ 1361, 1651, 2201-2202, and this Court's general equitable powers.

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1361.

8. This Court has personal jurisdiction over Defendant FDA because it resides within this District.

9. Venue in this District is proper under 28 U.S.C. § 1391(e).

STATUTORY AND REGULATORY BACKGROUND

10. Section 505(j)(7)(A)(i) of the FDC Act (21 U.S.C. § 355(j)(7)(A)(i)) requires that FDA publish in the Orange Book three distinct pieces of information:

a. (I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) of this section before September 24, 1984;

b. (II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

c. (III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

11. Each subsection of Section 505(j)(7)(A)(i) imposes a discrete nondiscretionary statutory duty on FDA. The latter two subsections are at issue in this case, and specifically Subsection)(III).

12. FDA has stated in its regulations and elsewhere that it fulfills the statutory duty in Section 505(j)(7)(A)(i)(III) "through the use of therapeutic equivalence codes in the list." FDA, Proposed Rule, Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28,872, 28,911 (July 10, 1989) (internal citations omitted); *see also* 21 C.F.R. § 320.24(a) ("Information on bioequivalence requirements for specific products is included in the current edition of [the Orange Book]").

13. Section 505(j)(7)(A)(ii) mandates that "[e]very thirty days after the publication of the first list under clause (i), the Secretary shall revise the list to include each drug which has been approved." The obligation to revise the list "under clause (i)" includes Subsection (i)(III), which FDA has said it meets through the publication of TE codes in the Orange Book.

14. As FDA explained in the Orange Book Preface: "To contain drug costs, virtually every state has adopted laws and/or regulations that encourage the substitution of drug products. These state laws generally require either that substitution be limited to drugs on a specific list (the positive formulary approach) or that it be permitted for all drugs except those prohibited by a particular list (the negative formulary approach). Because of the number of requests in the late 1970s for FDA assistance in preparing both positive and negative formularies, it became apparent that FDA could not serve the needs of each state on an individual basis." Orange Book Preface at iv (34th ed., 2014). Accordingly, in 1980, FDA started publishing a list of approved products that FDA considered therapeutically equivalent. As FDA has explained, "Drug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and

if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling." *Id.* at vii. As of 1984, FDA's practice of publishing a list with TE information was mandated by the Hatch-Waxman Amendments to the FDC Act.

15. According to FDA, it assigns A codes to"[d]rug products that FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products." *Id.* at xiii. "AB" rated products are those therapeutically equivalent products for which "actual or potential bioequivalence problems have been resolved with adequate *in vivo* and/or *in vitro* evidence supporting bioequivalence." *Id.*

16. "In contrast, "B" Codes are assigned to "[d]rug products that FDA, at this time, considers not to be therapeutically equivalent to other pharmaceutically equivalent products." *Id.* at xvii"

17. By failing to publish a TE code for Perrigo's Product, FDA is in violation of the law.

FACTUAL BACKGROUND

18. FDA approved Perrigo's Product on or about January 31, 2013, under NDA No. 203098, which Perrigo submitted pursuant to FDC Act § 505(b)(2) (21 U.S.C. § 355(b)(2)), and which FDA determined to be bioequivalent to the listed drug relied on for approval, AndroGel® (testosterone gel) 1%, based on data and information contained in Perrigo's NDA.

19. In partial compliance with its statutory duty, FDA has listed in the Orange Book the name of the Perrigo product, its approval date, and its NDA number. FDA has not, however, published a TE code for the Perrigo Product.

20. On or about April 18, 2013, more than 2.5 months after FDA approved Perrigo's Product, Perrigo wrote to FDA and requested that FDA fulfill its statutory obligation by assigning Perrigo's Product an "AB" rating, reflecting that Perrigo's Product is therapeutically equivalent to, and substitutable for, the listed drug relied on for approval.

21. On or about September 13, 2013, more than 7 months after FDA approved Perrigo's Product, Perrigo again wrote to FDA requesting that the Agency fulfill its statutory obligation and assign a TE rating to Perrigo's Product. While reiterating its request for an AB rating, Perrigo noted that notwithstanding any potential questions regarding an AB rating, Perrigo's Product was entitled to either an "A" or "B" rating, and under either such rating, Perrigo would not incur user fees of nearly $1 million.

22. On or about February 18, 2014, Perrigo yet again wrote to FDA, and attached a draft version of this very complaint. Perrigo explained that "[g]iven FDA's longstanding delay to take statutorily-required action, despite repeated requests by Perrigo for prompt Agency action, Perrigo has been left with no option other than to consider litigation against FDA" unless it received a satisfactory response from the Agency by March 19, 2014, which it did not.

23. FDA's unlawful and unreasonable delay in assigning a TE rating in the Orange Book has caused actual and imminent harm to Perrigo.

PLAINTIFF'S CLAIMS FOR RELIEF

Count I: Violation of the FDC Act and APA–Unreasonable Delay in FDA's Failure to Publish a TE rating

24. The allegations in paragraphs 1 to 23 are incorporated herein by reference.

25. Section 505(j)(7)(A)(i)(III) mandates that FDA publish "whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published." This section imposes a clear statutory duty on FDA and FDA has stated that it fulfills this obligation through the publication of TE ratings. *See* 54 Fed. Reg. at 28,911 ("The 1984 Amendments provide that FDA shall publish in the list of approved drugs a statement of whether, for each drug, in vitro or in vivo studies are required to show bioequivalence. FDA satisfies this requirement through the use of therapeutic equivalence codes in the list.") (internal citations omitted).

26. Section 505(j)(7)(A)(ii) mandates that "[e]very thirty days . . . the Secretary shall revise the list to include each drug which has been approved." The obligation to revise the list includes the obligation to update information required under Section 505(j)(7)(A)(i)(III), which FDA has said it meets through the publication of therapeutic equivalence codes in the Orange Book.

27. By failing to publish a TE code for Perrigo's Product, FDA is in violation of the law.

28. 5 U.S.C. § 551(13) provides that "agency action" is defined as including those instances where an agency has failed to act. 5 U.S.C. § 702 authorizes a person suffering legal wrong because of agency action to seek judicial review.

29. 5 U.S.C. § 706(1) grants a court the power to compel an agency to act when its delay or inaction is deemed unreasonable, providing, "[t]he reviewing court shall – (1) compel agency action unlawfully withheld or unreasonably delayed. . . ."

30. FDA has unlawfully failed to publish a TE rating for Perrigo's Product, and its failure to act is thus arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, and without observance of procedure required by law, in violation of the APA. *See* 5 U.S.C. §§ 706(2)(A), (D).

Count II: Declaratory Judgment 28 U.S.C. §§ 2201-2202
FDA Unreasonable Delay

31. The allegations in paragraphs 1 to 30 are incorporated herein by reference.

32. There is a case of actual controversy within the jurisdiction of this Court.

33. Perrigo seeks a declaration from this Court that FDA has violated the FDC Act by failing to publish a TE rating for Perrigo's Product and ordering FDA to promptly do so.

Count III: Mandamus

34. The allegations in paragraphs 1 to 33 are incorporated herein by reference.

35. Pursuant to 28 U.S.C. § 1651, this Court should compel FDA to perform a duty owed to Perrigo, namely to immediately publish a TE rating for Perrigo's Product.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that this Court grant the following relief:

36. Enter a mandatory injunction that compels FDA to publish a TE rating for Perrigo's Product as soon as possible and in any event no later than 30 days from the date the injunction is entered.

37. Enter a declaratory judgment that the Defendant's failure to provide the non-discretionary statutorily-required published TE rating constitutes agency action unlawfully withheld and unreasonably delayed.

38. Award Plaintiff its costs and attorneys' fees.

39. Award such other relief as may be just and proper.

Dated: March 21, 2014

Respectfully submitted,

PERRIGO ISRAEL PHARMACEUTICALS LTD. AND PERRIGO COMPANY

By: /s/ J.P. Ellison

James P. Ellison (D.C. Bar No. 477931)
Kurt R. Karst (D.C. Bar No. 482615)
Hyman, Phelps & McNamara, P.C.
700 13th Street, N.W., Suite 1200
Washington, D.C. 20005
Phone: (202) 737-5600
Fax: (202) 737-9329

Attorneys for Perrigo Israel Pharmaceuticals Ltd. and Perrigo Company