

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 4 ATLANTA FEDERAL CENTER 61 FORSYTH STREET ATLANTA, GEORGIA 30303-8960

SEP 1 3 2019

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Mr. Paul Daniels EHS Specialist UPM Pharmaceuticals, Inc. 501 Fifth Street Bristol, Tennessee 37620

Re:

In the Matter of UPM Pharmaceuticals, Inc.

Consent Agreement and Final Order Docket No. CAA-04-2019-9955(b)

Dear Mr. Daniels:

Enclosed is a copy of the ratified Consent Agreement and Final Order (CAFO) in the above-referenced matter. The original CAFO has been filed with the Regional Hearing Clerk and served on the parties as directed in Section 22.05(a) of the Consolidated Rules of Practice, as amended. 40 C.F.R. Part 22.

Please refer to Section VII (Terms of Payment) of the CAFO for penalty information and payment requirements. To ensure proper processing, the Respondent's Name and Docket Number for this case, identified above and in the CAFO, should be noted on any cashier's or certified checks submitted in payment of the penalty. If you have any questions regarding the processing of UPM's penalty may be directed to Jessica Henderson, Cincinnati Finance Office, at (513) 487-2718.

If you have any questions about this matter or the process outlined above, please contact Seneca Anderson at (404) 562-9050 or Gretchen Frizzell, Associate Regional Counsel, at (404) 562-8089.

Sincerely,

César A. Zapata

Acting Chief

Air Enforcement Branch

Enclosure

cc (w/ enclosure):

John C. Bowles

Vice President / General Counsel

UPM Pharmaceuticals, Inc.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY Region 4

| In the Matter of: | | |
|------------------------------------|--|--|
| Gregory Pharmac d/b/a UPM Pharm | ceutical Holdings, Inc. naceuticals, Inc. | |
| Respondent. | | |
| | | |

Docket No. CAA-04-2019-9955(b)

CONSENT AGREEMENT

I. NATURE OF ACTION

- 1. This is an administrative penalty assessment proceeding brought under Section 113(d) of the Clean Air Act ("CAA" or the "Act"), 42 U.S.C. § 7413(d), and Sections 22.13(b) and 22.18 of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (Consolidated Rules), as codified at Title 40 of the Code of Federal Regulations (C.F.R.), Part 22.
- This Consent Agreement and the attached Final Order shall collectively be referred to as the CAFO.
- 3. Having found that settlement is consistent with the provisions and objectives of the Act and applicable regulations, the Parties have agreed to settle this action pursuant to 40 C.F.R. § 22.18 and consent to the entry of this CAFO without adjudication of any issues of law or fact herein.

II. PARTIES

- 4. Complainant is the Director of the Enforcement and Compliance Assurance Division, who has been delegated the authority on behalf of the Administrator of the United States Environmental Protection Agency (EPA) to enter into this CAFO pursuant to 40 C.F.R. Part 22 and Section 113(d) of the Act.
- 5. Respondent is Gregory Pharmaceutical Holdings Inc. d/b/a/ UPM Pharmaceuticals, Inc. (UPM), a corporation doing business in the State of Tennessee. This proceeding pertains to Respondent's facility located at 501 Fifth Street, Bristol, Tennessee 37620 (Facility).

III. GOVERNING LAW

- 6. Any person who violates Section 112 of the CAA, 42 U.S.C. § 7412, or rule promulgated thereunder, may be assessed a civil penalty pursuant to Section 113(d) of the Act, 42 U.S.C. § 7413(d), and 40 C.F.R. Part 19. Each day a violation continues may constitute a separate violation. Civil penalties under Section 113(d) of the Act, 42 U.S.C. § 7413(d), may be assessed by an administrative order.
- 7. In Section 112(b) of the CAA, Congress established a list of hazardous air pollutants (HAPs). 42 U.S.C. § 7412(b)(1).
- 8. Congress directed the EPA to publish a list of categories and subcategories of major sources and area sources of HAPs. 42 U.S.C. § 7412(c).
- 9. A "major source" of HAPs is a stationary source that emits or has the potential to emit more than 10 tons per year of any single HAP or more than 25 tons per year of any combination of HAPs. An "area source" of HAPs is a stationary source of HAPs that is not a major source. 42 U.S.C. § 7412(a); 40 C.F.R. § 63.2.
- 10. A "stationary source" is any building, structure, facility, or installation that emits or may emit any air pollutant. 42 U.S.C. § 7412(a)(3); 40 C.F.R. § 63.2.
- 11. Congress directed the EPA to establish emission standards for each category or subcategory of major sources and area sources of HAPs. 42 U.S.C. § 7412(d).
- 12. These standards are known as National Emission Standards for Hazardous Air Pollutants (NESHAP), or maximum achievable control technology (MACT) standards, and are compiled primarily at 40 C.F.R. Part 63.
- 13. NESHAPs are effective upon promulgation. 42 U.S.C. § 7412(d)(10). After the effective date of a NESHAP, no person shall operate a source subject to the NESHAP in violation of such NESHAP. 42 U.S.C. § 7412(i)(3).
- 14. General NESHAP provisions that apply, generally, to all source categories, are located in 40 C.F.R. Part 63, Subpart A.
- 15. The NESHAP for Pharmaceuticals Production was initially promulgated at 63 Fed. Reg. 50280 (Sept. 21, 1998) and is codified at 40 C.F.R. §§ 63.1250–63.1261 and Tables 1 through 9 (Subpart GGG).
- 16. Owners and operators of pharmaceutical manufacturing units located at major sources of HAPs are subject to Subpart GGG. 40 C.F.R. § 63.1250.
- 17. Among other things, Subpart GGG requires affected sources to establish and maintain operating parameters for HAP emission control devices. 40 C.F.R. § 63.1258.

- 18. Section 112(I) of the CAA allows states to develop and submit to EPA for approval programs to implement and enforce NESHAPs, but EPA continues to have authority to enforce such standards. 42 U.S.C. §§ 7412(I)(1), 7412(I)(7), and 7413.
- 19. EPA and the United States Department of Justice jointly determined that this matter although it involves alleged violations that occurred more than one year before the initiation of this proceeding, is appropriate for an administrative penalty assessment. 42 U.S.C. § 7413(d); 40 C.F.R. § 19.4.
- 20. The notice requirements of Section 113(a) of the CAA, 42 U.S.C. § 7413(a), do not apply to the alleged violations in this Consent Agreement.

IV. FINDINGS OF FACTS

- 21. The UPM Facility is located at 501 Fifth Street, Bristol, Tennessee, and is a "stationary source" as that term is defined in Section 302(z) of the Act, 42 U.S.C. § 7602(z), and a "major stationary source" of HAPs.
- 22. UPM owns or operates multiple pharmaceutical manufacturing process units at its Facility and is subject to Subpart GGG.
- 23. UPM purchased the Facility from King Pharmaceuticals, LLC on or around July 1, 2013, subject to entry of a Consent Decree (Civil Action Number 2:13-cv-00178) entered into by and between King Pharmaceuticals, LLC, with the EPA and the State of Tennessee on August 22, 2013.
- 24. The Consent Decree required, among other things, compliance with Subpart GGG and submission of quarterly periodic reports.
- 25. The periodic reports were required to include, among other things, any exceedances of control device operating parameters.
- 26. Periodic reports submitted by Respondent between September 18, 2014, and December 20, 2016, indicated a total of 96 days of parameter exceedances. In addition, UPM used parameter values when the control device was not controlling HAP emissions to calculate the daily average.

V. ALLEGED VIOLATIONS

- 27. Respondent is a "person" as defined in Section 302(e) of the Act. 42 U.S.C. § 7602(e).
- 28. Pursuant to 40 C.F.R. § 63.1258, UPM is required to establish and maintain operating parameter levels for HAP emission control devices. In a May 2014 stack test, parameters were established for the regenerative thermal oxidizer (RTO), pursuant to 40 C.F.R. § 63.1258(b)(1)(vii), and the scrubber, pursuant to 40 C.F.R. § 63.1258(b)(1)(ii). The minimum temperature of 1,682 degrees Fahrenheit for the RTO demonstrated compliance with the 98% HAP removal requirement in 40 C.F.R. § 63.1254(a)(3). The minimum flowrate of 254.6 gallons per minute and minimum pH of 9.4 for the scrubber demonstrated compliance with the 95% hydrogen halide and halogen removal requirement in 40 C.F.R. § 63.1252(g)(1).

- a. In the periodic reports between September 18, 2014, and December 20, 2016, UPM reported 96 days in which these parameters were exceeded (43 days for the minimum temperature, 2 days for the minimum pH, and 51 days for the minimum scrubber flowrate).
- b. UPM therefore failed to maintain operating parameter levels on its HAP emission control devices, as required by 40 C.F.R. § 63.1258.
- 29. Pursuant to 40 C.F.R. § 63.1258(b)(2)(iii), "monitoring values taken during periods in which the control devices are not functioning in controlling emissions, as indicated by periods of no flow, shall not be considered in the averages."
 - a. UPM has used monitoring values taken during periods of no flow, when the control devices were not functioning to control emissions, in calculating its daily average to demonstrate compliance.
 - b. UPM therefore has failed to comply with 40 C.F.R. § 63.1258(b)(2)(iii).

VI. STIPULATIONS

- 30. The issuance of this CAFO simultaneously commences and concludes this proceeding. 40 C.F.R. § 22.13(b).
- 31. For the purpose of this proceeding, as required by 40 C.F.R. § 22.18(b)(2), Respondent:
 - a. admits that EPA has jurisdiction over the subject matter alleged in this CAFO;
 - b. neither admits nor denies the factual allegations set forth in Section IV (Findings of Facts) of this CAFO;
 - consents to the assessment of a civil penalty as stated below;
 - d. consents to the conditions specified in this CAFO;
 - e. waives any right to contest the allegations set forth in Section V (Alleged Violations) of this CAFO; and
 - f. waives its rights to appeal the Final Order accompanying this CAFO.
- 32. For the purpose of this proceeding, Respondent:
 - a. agrees that this CAFO states a claim upon which relief may be granted against Respondent;
 - acknowledges that this CAFO constitutes an enforcement action for purposes of considering Respondent's compliance history in any subsequent enforcement actions;

- c. waives any rights it may possess at law or in equity to challenge the authority of EPA to bring a civil action in a United States District Court to compel compliance with the CAFO, and to seek an additional penalty for such noncompliance, and agrees that federal law shall govern in any such civil action;
- d. by executing this CAFO, certifies to the best of its knowledge that upon implementation of the alternative monitoring procedure (requested on August 21, 2019, in a letter to Chief of the Community and Air Toxics Section of the Air and Radiation Division, EPA Region 4), as approved by the EPA, Respondent will be in compliance with all relevant requirements of the Act and its implementing regulations, and that all violations alleged herein, which are neither admitted nor denied, have been corrected;
- e. waives any right it may have pursuant to 40 C.F.R. § 22.8 to be present during any discussions with, or to be served with and reply to, any memorandum or communication addressed to EPA officials where the purpose of such discussion, memorandum, or communication is to persuade such official to accept and issue this CAFO; and
- f. agrees to comply with the terms of the CAFO.
- 33. In accordance with 40 C.F.R. § 22.5, the individuals named in the certificate of service are authorized to receive service related to this proceeding and the parties agree to receive service by electronic means.

VII. TERMS OF PAYMENT

- 34. Respondent consents to the payment of a civil penalty, which was calculated in accordance with the Act, in the amount of \$81,000.00, which is to be paid within thirty (30) calendar days of the Effective Date of this CAFO.
- 35. Payment(s) shall be made by cashier's check, certified check, by electronic funds transfer (EFT), or by Automated Clearing House (ACH) (also known as REX or remittance express). If paying by check, the check shall be payable to: Treasurer, United States of America, and the Facility name and docket number for this matter shall be referenced on the face of the check. If Respondent sends payment by the U.S. Postal Service, the payment shall be addressed to:

United States Environmental Protection Agency Fines and Penalties Cincinnati Finance Center P.O. Box 979077 St. Louis, Missouri 63197-9000

If Respondent sends payment by non-U.S. Postal express mail delivery, the payment shall be sent to:

U.S. Bank Government Lockbox 979077 U.S. EPA Fines & Penalties 1005 Convention Plaza SL-MO-C2-GL St. Louis, Missouri 63101 (314) 425-1818

If paying by EFT, Respondent shall transfer the payment to:

Federal Reserve Bank of New York
ABA: 021030004
Account Number: 68010727
SWIFT address: FRNYUS33
33 Liberty Street
New York, New York 10045
Field Tag 4200 of the Fedwire message should read: "D 68010727 Environmental Protection Agency"

If paying by ACH, Respondent shall remit payment to:

US Treasury REX / Cashlink ACH Receiver
ABA: 051036706
Account Number: 310006, Environmental Protection Agency
CTX Format Transaction Code 22 – checking
Physical location of US Treasury facility:
5700 Rivertech Court
Riverdale, Maryland 20737
Contact: John Schmid, (202) 874-7026
REX (Remittance Express): 1-866-234-5681

36. Respondent shall send proof of payment, within 24 hours of payment of the civil penalty, to:

Regional Hearing Clerk U.S. EPA Region 4 61 Forsyth Street, S.W. Atlanta, Georgia 30303-8960

and

Seneca Anderson
Air and Radiation Division
Air Analysis and Support Branch
U.S. EPA Region 4
61 Forsyth Street, S.W.
Atlanta, Georgia 30303-8960
anderson.seneca@epa.gov

37. "Proof of payment" means, as applicable, a copy of the check, confirmation of credit card or debit card payment, confirmation of wire or automated clearinghouse transfer, and any other

- information required to demonstrate that payment has been made according to EPA requirements, in the amount due, and identified with the Facility name and Docket No. CAA-04-2019-9955(b).
- 38. Pursuant to 31 U.S.C. § 3717, 31 C.F.R. § 901.9, and 40 C.F.R. § 13.11, if Respondent fails to remit the civil penalty as agreed to herein, EPA is entitled to assess interest and penalties on debts owed to the United States and a charge to cover the costs of processing and handling the delinquent claim. Accordingly, EPA may require the Respondent to pay the following amounts on any amount overdue:
 - a. <u>Interest</u>. Interest will begin to accrue on the civil penalty from the Effective Date of this CAFO. If the civil penalty is paid within 30 days, Interest is waived. However, if the civil penalty is not paid in full within 30 days of the Effective Date of this CAFO, Interest will continue to accrue on any unpaid portion until the unpaid portion of the civil penalty and accrued Interest is paid. Interest will be assessed at the rate of the United States Treasury tax and loan rate, as established by the Secretary of the Treasury, in accordance with 31 U.S.C. § 3717(a)(1), 31 C.F.R. § 901.9(b), and 40 C.F.R. § 13.11(a).
 - b. Non-Payment Penalty. On any portion of a civil penalty more than ninety (90) calendar days past due, Respondent must pay a non-payment penalty of not more than six percent (6%) per annum, which will accrue from the date the penalty payment became due under Section VII and is not paid in full, as provided in 31 U.S.C. § 3717(e)(2) and 31 C.F.R. § 901.9(d). This non-payment penalty is in addition to charges which accrue or may accrue under subparagraphs (a) and (c) and will be assessed monthly. 40 C.F.R. § 13.11(c).
 - c. Monthly Handling Charge. Respondent must pay a late payment handling charge to cover the administrative costs of processing and handling the delinquent claim, based on either actual or average cost incurred. 31 C.F.R. § 901.9(c), and 40 C.F.R. § 13.11(b). Administrative costs will be assessed monthly throughout the period the debt is overdue except as provided by 40 C.F.R. § 13.12.
- 39. If Respondent fails to timely pay any portion of the penalty assessed under this CAFO, EPA may request the Attorney General to bring a civil action in an appropriate district court to recover: (a) the amount assessed; (b) interest at rates established pursuant to 26 U.S.C. § 6621(a)(2); (c) the United States' attorneys' fees and enforcement expenses; and (d) a 10 percent quarterly nonpayment penalty, 42 U.S.C. § 7413(d)(5), 31 C.F.R. § 901.9(d), and 40 C.F.R. § 13.11(c). In any such action, the validity, amount, and appropriateness of the penalty and of this CAFO shall not be subject to review.
- 40. In addition to what is stated in the prior Paragraph, if Respondent fails to timely pay any portion of the penalty assessed under this CAFO, EPA may:
 - a. refer the debt to a credit reporting agency or a collection agency, 42 U.S.C. § 7413(d)(5), 40 C.F.R. §§ 13.13 and 13.14;
 - b. collect the debt by administrative offset (i.e., the withholding of money payable by the United States to, or held by the United States for, a person to satisfy the debt the person

owes the Government), which includes, but is not limited to, referral to the Internal Revenue Service for offset against income tax refunds, 40 C.F.R. Part 13, Subparts C and H;

- c. suspend or revoke Respondent's licenses or other privileges, or suspend or disqualify Respondent from doing business with EPA or engaging in programs EPA sponsors or funds, 40 C.F.R. § 13.17; and/or
- d. refer the debt to the Department of Justice after having taken aggressive collection action, as provided in 40 C.F.R. § 13.33.
- 41. Penalties paid pursuant to this CAFO shall not be deductible for purposes of federal taxes.

VIII. EFFECT OF CAFO

- 42. In accordance with 40 C.F.R. § 22.18(c), Respondent's full compliance with this CAFO shall only resolve Respondent's liability for federal civil penalties for the violations and facts specifically alleged above.
- 43. Full payment of the civil penalty, as provided in Section VII (Terms of Payment), shall not in any case affect the right of EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law. 40 C.F.R. § 22.18(c).
- 44. Any violation of this CAFO may result in a civil judicial action for civil penalties as provided in Section 113(b) of the Act, 42 U.S.C. § 7413(b), as well as criminal sanctions as provided in Section 113(c) of the Act, 42 U.S.C. § 7413(c). EPA may use any information submitted under this CAFO in an administrative, civil judicial, or criminal action.
- 45. Nothing in this CAFO shall relieve Respondent of the duty to comply with all applicable provisions of the Act and other federal, state, or local laws or statutes, nor shall it restrict EPA's authority to seek compliance with any applicable laws or regulations, nor shall it be construed to be a ruling on, or determination of, any issue related to any federal, state, or local permit, except as expressly provided herein.
- 46. Nothing herein shall be construed to limit the power of EPA to undertake any action against Respondent or any person in response to conditions that may present an imminent and substantial endangerment as provided under the Act.
- 47. The terms, conditions, and compliance requirements of this CAFO may not be modified or amended except upon the written agreement of both Parties, and approval of the Regional Judicial Officer.
- 48. The provisions of this CAFO shall apply to and be binding upon Respondent and its officers, directors, employees, agents, trustees, servants, authorized representatives, successors, and assigns.

- 49. Any change in the legal status of the Respondent, or change in ownership, partnership, corporate or legal status relating to the Facility, will not in any way alter Respondent's obligations and responsibilities under this CAFO.
- 50. By signing this Consent Agreement, Respondent acknowledges that this CAFO will be available to the public and agrees that this CAFO does not contain any confidential business information or personally identifiable information.
- 51. By signing this Consent Agreement, the Complainant and the undersigned representative of Respondent each certify that he or she is fully authorized to execute and enter into the terms and conditions of this CAFO and has the legal capacity to bind the party he or she represents to this CAFO.
- 52. By signing this Consent Agreement, both Parties agree that each party's obligations under this CAFO constitute sufficient consideration for the other party's obligations.
- 53. By signing this Consent Agreement, Respondent certifies that the information it has supplied concerning this matter was at the time of submission, and continues to be, true, accurate, and complete for each such submission, response, and statement. Respondent acknowledges that there are significant penalties for submitting false or misleading information, including the possibility of fines and imprisonment for knowing submission of such information, under 18 U.S.C. § 1001.
- 54. EPA also reserves the right to revoke this CAFO and settlement penalty if and to the extent that EPA finds, after signing this CAFO, that any information provided by Respondent was materially false or inaccurate at the time such information was provided to EPA. If such false or inaccurate material was provided, EPA reserves the right to assess and collect any and all civil penalties for any violation described herein. EPA shall give Respondent notice of its intent to revoke, which shall not be effective until received by Respondent in writing.
- 55. It is the intent of the parties that the provisions of this CAFO are severable. If any provision or authority of this CAFO or the application of this CAFO to any party or circumstances is held by any judicial or administrative authority to be invalid or unenforceable, the application of such provisions to other parties or circumstances and the remainder of the CAFO shall remain in force and shall not be affected thereby.
- 56. Unless specifically stated otherwise in this CAFO, each party shall bear its own attorney's fees, costs, and disbursements incurred in this proceeding.

IX. EFFECTIVE DATE

57. This CAFO shall become effective after execution of the Final Order by the Regional Judicial Officer, on the date of filing with the Hearing Clerk.

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Complainant and Respondent will Each Sign on Separate Pages

The foregoing Consent Agreement In the Matter of Gregory Pharmaceutical Holdings, Inc. d/b/a/ UPM Pharmaceuticals, Inc., Docket No. CAA-04-2019-9955(b), is Hereby Stipulated, Agreed, and Approved for Entry.

FOR RESPONDENT:

| | JCB | | |
|---------------|----------------------------|------------|------|
| | T. 200 | 8-29-à | 2019 |
| Signature | | Date | |
| Printed Name: | JOHN C BOWLES | | |
| Title: | VICE PRESIDENT /GENERAL (| _ | |
| Address: | 501 FIFTH STREET , BRISTOL | , TN 37620 | |

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FOR COMPLAINANT:

Date

Suzanne G. Rubini Acting Director

Enforcement and Compliance Assurance Division U.S. Environmental Protection Agency, Region 4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 4

| In the Matter of: | |
|--|--------------------------------|
| Gregory Pharmaceutical Holdings, Inc. d/b/a/ UPM Pharmaceuticals, Inc. | Docket No. CAA-04-2019-9955(b) |
| Respondent. | FINAL ORDER |

The Regional Judicial Officer is authorized to ratify this Consent Agreement which memorializes a settlement between Complainant and Respondent. 40 C.F.R. §§ 22.4(b) and 22.18(b)(3). The foregoing Consent Agreement is, therefore, hereby approved, ratified and incorporated by reference into this Final Order in accordance with the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits, 40 C.F.R. Part 22.

The Respondent is hereby ORDERED to comply with all of the terms of the foregoing Consent Agreement effective immediately upon filing of this Consent Agreement and Final Order with the Regional Hearing Clerk. This Final Order disposes of this matter pursuant to 40 C.F.R. §§ 22.18 and 22.31.

BEING AGREED, IT IS SO ORDERED this 12th day of September, 20

Tanya Flovd

Regional Judicial Officer

CERTIFICATE OF SERVICE

I certify that the foregoing "Consent Agreement" and "Final Order," in the Matter of Gregory Pharmaceutical Holdings, Inc. d/b/a/ UPM Pharmaceuticals, Inc., Docket No. CAA-04-2019-9955(b), were filed and copies of the same were mailed to the parties as indicated below.

Via United Parcel Service and Electronic Mail:

Paul Daniels EHS Specialist UPM Pharmaceuticals 501 5th Street Bristol, Tennessee 37620 pdaniels@upm-inc.com

John Bowles
Vice President, General Counsel
UPM Pharmaceuticals
501 Fifth Street
Bristol, Tennessee 37620
bowles@upm-inc.com

Via EPA's internal email:

Seneca Anderson U.S. EPA Region 4 61 Forsyth Street, S.W. Atlanta, Georgia 30303-8960 anderson.seneca@epa.gov

Gretchen Frizzell U.S. EPA Region 4 61 Forsyth Street, S.W. Atlanta, Georgia 30303-8960 frizzell.gretchen@epa.gov

9/13/19

DATE

Patricia A. Bullock, Regional Hearing Clerk

U.S. EPA Region 4

61 Forsyth Street, S.W.

Atlanta, Georgia 30303-8960



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 4 ATLANTA FEDERAL CENTER 61 FORSYTH STREET ATLANTA, GEORGIA 30303-8960

SEP 1 3 2019

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If you have any questions about this matter or the process outlined above, please contact Seneca Anderson at (404) 562-9050 or Gretchen Frizzell, Associate Regional Counsel, at (404) 562-8089.

Sincerely,

César A. Zapata

Acting Chief

Air Enforcement Branch

Enclosure

cc (w/ enclosure):

John C. Bowles

Vice President / General Counsel

UPM Pharmaceuticals, Inc.