U.S. FOOD & DRUG ADMINISTRATION

VIA UNITED PARCEL SERVICE AND E-MAIL

Armata Pharmaceuticals, Inc.
Attention: Vicki White, Senior Director of Clinical Operations
4503 Glencoe Avenue
Marina del Ray, California 90292
vwhite@armatapharma.com

Re: Submission of Clinical Trial Results Information Pursuant to 42 U.S.C. 282(j)
FDA Reference Number: CDER-2022-113
NCT03196219, NCT03004365, and NCT03052842

Dear Ms. White:

Based on an initial review of Food and Drug Administration (FDA) records, information from the ClinicalTrials.gov data bank operated by the National Library of Medicine (a part of the National Institutes of Health), and any available public information, it appears that Armata Pharmaceuticals, Inc. is the "responsible party"[1] for the above-identified clinical trials, which appear to be "applicable clinical trials"[2] subject to the requirements of section 801 of the Food and Drug Administration Amendments Act of 2007, including its implementing regulations in 42 CFR part 11. A responsible party for an applicable clinical trial is required to submit to the ClinicalTrials.gov data bank certain results information for the clinical trial; such results information generally must be submitted no later than one year after the primary completion date[3] of the applicable clinical trial, unless the responsible party has submitted a timely

[1] *See* section 402(j)(1)(A)(ix) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(1)(A)(ix)) and 42 CFR 11.10 for the definition of "responsible party."
[2] *See* section 402(j)(1)(A)(i)-(iii) of the PHS Act (42 U.S.C. 282(j)(1)(A)(i)-(iii)) and 42 CFR 11.10 for the definition of "applicable clinical trial."
[3] *See* 42 CFR 11.10 for the definition of "primary completion date." *See also* section 402(j)(1)(A)(v) of the PHS Act (42 U.S.C. 282(j)(1)(A)(v)), which defines "completion date." As reflected in 42 CFR 11.10, the terms "primary completion date" and "completion date" are synonymous for purposes of 42 CFR part 11.

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certification of delay, a request for an extension for good cause, or a request for a waiver of the requirements for submission of results information.[4]

Pursuant to 42 CFR 11.44(c), a responsible party may submit a timely certification for delayed submission of results information for an applicable clinical trial that studies an FDA-regulated drug product that was not approved by FDA for any use before the primary completion date, and for which the sponsor intends to continue with product development and is either seeking, or may at a future date seek, FDA approval of the drug product. However, in order to be timely, any such certification for delayed submission of results information must be submitted before the standard submission deadline. If a timely certification for delayed submission of results information is submitted under 42 CFR 11.44(c)(1), the deadline for submitting results information is 30 calendar days after the earlier of (1) the date on which FDA approves the drug product for any use that is studied in the applicable clinical trial, or (2) the date on which the marketing application or premarket notification is withdrawn without resubmission for not less than 210 calendar days. With such certification for delayed submission of results information, the responsible party must submit results information not later than two years after the date on which the certification was submitted, except to the extent that 42 CFR 11.44(d) applies.

FDA has identified potential noncompliance related to the above-identified clinical trials, titled as follows:

- C3J17-206-00, "A Phase 2, Open-label and Single-Blind Study to Evaluate the Microbiology, Safety and Tolerability of C16G2 Varnish and Strip Administered in Multiple Doses to Adolescent and Adult Dental Subjects," evaluating the oral microbiology, safety, and tolerability of multiple C16G2 varnish and strip applications in subjects between the ages of 12 and 75 years

- C3J16-V204-00, "A Phase 2, Single-blind, Randomized, Placebo-controlled Study to Evaluate the Safety and Microbiology of C16G2 Varnish Administered in Multiple Doses to Adolescent and Adult Dental Subjects," evaluating the safety and oral microbiology of C16G2 varnish application in human subjects between the ages of 12 and 75 years

- C3J16-S205-00, "A Phase 2, Single-blind, Randomized, Placebo-controlled Study to Evaluate the Microbiology, Safety and Tolerability of C16G2 Strip Administered in Multiple Doses to Adolescent and Adult Dental Subjects," evaluating the oral microbiology and safety of multiple C16G2 strip applications in subjects between the ages of 12 and 75 years

[4] *See* section 402(j)(3)(E) and (H) of the PHS Act (42 U.S.C. 282(j)(3)(E) and (H)) and 42 CFR part 11, subpart C for results information submission requirements.

It appears that results information for the referenced applicable clinical trials has not been submitted to the ClinicalTrials.gov data bank. Your company should review its records of these clinical trials and determine whether your company submitted all required results information. If your company determines that results information is required and due for these clinical trials, please submit the results information promptly.

Failure to submit clinical trial information[5] required under section 402(j) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)), including information required under the regulations found in 42 CFR part 11, is a prohibited act under section 301(jj)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 331(jj)(2)). Beginning 30 calendar days after you receive this letter, FDA intends to further review and assess the above-identified clinical trials. If FDA determines that your company has failed to submit any clinical trial information required under section 402(j) of the PHS Act (42 U.S.C. 282(j)), including its implementing regulations in 42 CFR part 11, your company may receive from FDA a Notice of Noncompliance,[6] and FDA may thereafter initiate an administrative action seeking a civil money penalty.[7] In addition to civil money penalties, violations of section 301(jj) of the FD&C Act (21 U.S.C. 331(jj)) could result in other regulatory action, such as injunction and/or criminal prosecution, without further notice.

As requested, please review your company's clinical trial records and submit any required results information to the ClinicalTrials.gov data bank. You can access the ClinicalTrials.gov website at https://register.clinicaltrials.gov. If you have any questions about this letter, you may call Miah Jung, Pharm.D., M.S., at (240) 402-3728. Please have the FDA reference number provided at the top of this letter available when you call. Alternatively, you may e-mail FDA at CDER-OSI-Advisory@fda.hhs.gov. Please include the FDA reference number with any e-mail communications.

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[5] *See* section 402(j)(1)(A)(iv) of the PHS Act (42 U.S.C. 282(j)(1)(A)(iv)) and 42 CFR 11.10 for the definition of "clinical trial information."

[6] *See* section 402(j)(5)(C)(ii) of the PHS Act (42 U.S.C. 282(j)(5)(C)(ii)).

[7] Pursuant to section 303(f)(3)(A) of the FD&C Act (21 U.S.C. 333(f)(3)(A)), "[a]ny person who violates section 301(jj) [of the FD&C Act (21 U.S.C. 331(jj))] shall be subject to a civil monetary penalty of not more than $10,000 for all violations adjudicated in a single proceeding." Moreover, section 303(f)(3)(B) of the FD&C Act (21 U.S.C. 333(f)(3)(B)) provides that "[i]f a violation of section 301(jj) [of the FD&C Act (21 U.S.C. 331(jj))] is not corrected within the 30-day period following notification under section 402(j)(5)(C)(ii) [of the PHS Act (42 U.S.C. 282(j)(5)(C)(ii))], the person shall, in addition to any penalty under subparagraph (A), be subject to a civil monetary penalty of not more than $10,000 for each day of the violation after such period until the violation is corrected." These civil money penalty amounts reflect the amounts found in the statute. These amounts are updated annually to reflect inflation, as required by the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. No. 101-410, 104 Stat. 890 (1990) (codified as amended at 28 U.S.C. 2461, note 2(a)), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. No. 114-74, November 2, 2015). For the most up-to-date amounts, please see 45 CFR 102.3.

We request that you submit a written response to FDA within 30 calendar days after you receive this letter, stating the actions you have taken in response to this letter. If you believe that your company has complied with applicable requirements, please provide us with your reasoning and include any supporting information for our consideration. Please direct your response to the address below and include the FDA reference number in all correspondence relating to this matter.

Miah Jung, Pharm.D., M.S.
Branch Chief
Compliance Enforcement Branch
Division of Enforcement and Postmarketing Safety
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Building 51, Room 5352
10903 New Hampshire Avenue
Silver Spring, MD 20993

Sincerely yours,

{See appended electronic signature page}

Laurie Muldowney, M.D.
Deputy Director
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

LAURIE B MULDOWNEY
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