U.S. FOOD & DRUG ADMINISTRATION

PRE-NOTICE OF NONCOMPLIANCE LETTER – FAILURE TO SUBMIT RESULTS INFORMATION

VIA UNITED PARCEL SERVICE

February 28, 2020

Eben Clattenburg, M.D.
Emergency Department
Flagstaff Medical Center
1200 North Beaver Street
Flagstaff, Arizona 86001

Re: Submission of Clinical Trial Results Information Pursuant to 42 U.S.C. 282(j)
(FDA Reference Number: CDER-2020-102; NCT #02916927)

Dear Dr. Clattenburg:

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 (NLM), a part of the National Institutes of Health (NIH), and any available public information, it appears that you are the responsible party for the clinical trial titled "Intravenous Sub-dissociative Dose Ketamine Injection Versus Infusion for Analgesia in the Emergency Department: A Prospective, Randomized, Double-blind Placebo Controlled Trial." This trial is an applicable clinical trial that is 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.[1] The responsible party[2] for an applicable clinical trial is required to submit to the ClinicalTrials.gov data bank certain results information for such clinical trial, which generally must be submitted no later than one year after the primary completion date of the applicable clinical trial, unless the responsible party has submitted a certification of delay.[3] FDA has identified potential noncompliance related to the above-

[1] *See* section 402(j)(1)(A)(i) and (iii) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(1)(A)(i) and (iii)) and 42 CFR 11.10(a) for the definitions of *applicable clinical trial*.
[2] *See* section 402(j)(1)(A)(ix) of the PHS Act (42 U.S.C. 282(j)(1)(A)(ix)) and 42 CFR 11.10 for the definition of *responsible party*.
[3] *See* section 402(j)(3)(E) of the PHS Act (42 U.S.C. 282(j)(3)(E)) and 42 CFR part 11, subpart C.

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identified clinical trial that evaluated whether sub-dissociated dose ketamine (specifically Ketalar (ketamine hydrochloride), an FDA-approved drug), given as an infusion versus an intravenous push over one minute, has fewer and/or less severe adverse drug reactions and provides equivalent analgesia for subjects with moderate to severe pain in the Emergency Department. It appears that results information for the referenced applicable clinical trial has not been submitted to the ClinicalTrials.gov data bank. You should review your records for this clinical trial and determine whether you submitted all required results information. If you determine that results information is required and due for this clinical trial, please submit the results information promptly.

Failure to submit clinical trial information required under section 402(j) of the 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)). FDA intends to further review and assess the above-described clinical trial beginning 30 calendar days after you receive this letter. At that time, if FDA determines that you are not in compliance with all applicable requirements of section 402(j) of the PHS Act (42 U.S.C. 282(j)) and 42 CFR part 11, you will receive from FDA a Notice of Noncompliance,[4] and FDA may thereafter initiate an administrative action seeking a civil monetary penalty.[5] In addition to civil monetary penalties, violations of section 301(jj) of the FD&C Act (21 U.S.C. 331(jj)) could also result in other regulatory action without further notice, such as injunction and/or criminal prosecution.

As requested, please review your 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, please call Mark S. Miller, Pharm.D., at 301-796-2798 and have the FDA reference number provided at the top of this letter available when you call. If you prefer, you may e-mail Mark S. Miller at Mark.Miller2@fda.hhs.gov, and include the reference number with any e-mail communications.

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

[5] 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." The civil monetary penalty amounts listed in this letter reflect the amounts listed 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 that you have taken in response to this letter. If you believe that you have complied with applicable requirements, please provide us with your reasoning and any supporting information for our consideration. Please direct your response to the address below and include the reference number on all correspondence relating to this matter.

Mark S. Miller, Pharm.D., BCPS, RAC
CAPT, USPHS
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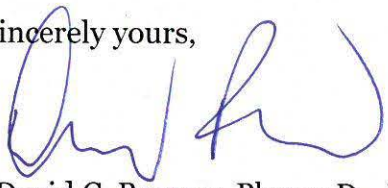
Sincerely yours,



/David C. Burrow, Pharm.D., J.D./
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Director
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