

**U.S. Food and Drug Administration**  
Protecting and Promoting *Your* Health

# Neuralight HD, LLC 4/14/16



Department of Health and Human Services

Public Health Service  
Food and Drug  
Administration  
Silver Spring, MD 20993

## WARNING LETTER

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Ref.: 16-HFD-45-04-01

ATTN: E. Conrad Hicks, M.D.  
Neuralight HD, LLC  
4221 East Chandler Boulevard, #119  
Phoenix, Arizona 85048

Dear Dr. Hicks:

This Warning Letter informs you of objectionable conditions observed during the U.S. Food and Drug Administration (FDA) inspection conducted at Neuralight HD, LLC between May 11 and May 20, 2015. Mr. Charles L. Larson, representing FDA, reviewed Neuralight's conduct as the sponsor of a clinical investigation (Protocol **(b)(4)**, "**(b)(4)**") of an investigational drug, **(b)(4)**.

This inspection is part of FDA's Bioresearch Monitoring Program, which includes inspections designed to evaluate the conduct of FDA-regulated research to ensure that the data are scientifically valid and accurate, and to help ensure that the rights, safety, and welfare of the human subjects of those studies have been protected.

At the conclusion of the inspection, Mr. Larson presented and discussed with you Form FDA 483, Inspectional Observations. We acknowledge receipt of your June 8, 2015, written response to the Form FDA 483.

From our review of the FDA Establishment Inspection Report, the documents submitted with that report, and your June 8, 2015, written response, we conclude that you did not adhere to the applicable statutory requirements and FDA regulations governing the conduct of clinical investigations and the protection of human

subjects. We wish to emphasize the following:

**Failure to submit an IND for the conduct of clinical investigations with an investigational new drug that is subject to 21 U.S.C. 355(i), 21 CFR 312.2(a) and (b), and 312.40(a) and (b).**

In relevant part, the Federal Food, Drug, and Cosmetic Act (FD&C Act) defines the term *drug* as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals” [21 U.S.C.

321(g)]. Neuralight studied the efficacy of **(b)(4)** for **(b)(4)** for a period of 13 weeks under Protocol **(b)(4)**. Because the product was intended for **(b)(4)**, it meets the definition of a drug under the FD&C Act.

To market a new drug lawfully, a sponsor must obtain FDA approval of either a new drug application or an abbreviated new drug application under Section 505 of the FD&C Act [21 U.S.C. 355]. An Investigational New Drug (IND) application allows a sponsor to obtain an exemption from this requirement in order to distribute an investigational drug [21 U.S.C. 355(i)]. FDA regulations require a sponsor to submit an IND application before conducting a clinical investigation of a drug in human subjects, unless the clinical investigation qualifies for an IND exemption under 21 CFR 312.2(b). That regulation provides an exemption from the requirement to obtain an IND before initiating a clinical investigation of a drug if all of the following exemption criteria are met:

- The drug product is lawfully marketed in the United States;
- The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use, and there is no intent to use the investigation to support any other significant change in the labeling of the drug;
- In the case of a lawfully marketed prescription drug, the investigation is not intended to support a significant change in the advertising for the drug;
- The investigation does not involve a route of administration, dosage level, use in a patient population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;
- The investigation is conducted in compliance with the requirements for institutional review set forth in 21 CFR 56 and with the requirements for informed consent set forth in 21 CFR 50; and
- The investigation is conducted in compliance with the requirements of 21 CFR 312.7.

Your clinical investigation of **(b)(4)** failed to meet at least the first criterion. The investigational drug Neuralight used to conduct its study under Protocol **(b)(4)** was a new, unapproved injectable drug, administered subcutaneously to human subjects on a daily basis over a 13-week period to treat **(b)(4)**. The investigational drug was not a lawfully marketed drug product in the United States and therefore was not exempt from the IND requirements. Before using the investigational drug in a clinical investigation, Neuralight was required to submit an IND to FDA, and to have an IND

in effect under 21 CFR 312.40. FDA records indicate that Neuralight failed to submit an IND before conducting the investigation under Protocol **(b)(4)**, a study in which twenty human subjects were enrolled and participated.

In your June 8, 2015, written response to the Form FDA 483, you stated that before initiating the **(b)(4)** study, you discussed it with an Institutional Review Board and with professional regulatory consultants, and that you used authoritative and publicly available resources to evaluate the need for the IND submission. You also stated that based on your evaluation, you concluded that an IND was not required because your investigational drug met the exemption criteria outlined in 21 CFR 312.2(b).

Although we acknowledge your efforts to seek professional advice, as the sponsor you are ultimately responsible for compliance with the IND requirements. By exposing human subjects to a new, unapproved drug without obtaining an IND, Neuralight jeopardized the safety of those subjects.

In your June 8, 2015, written response, you also indicated that Neuralight continues to consult as needed with clinical development professionals to help Neuralight comply with the federal regulatory requirements. We acknowledge your subsequent efforts to take appropriate corrective actions by submitting an IND application and by starting the formal process of a proposed clinical trial pathway with the FDA. However, starting the process to conduct a clinical trial under an IND does not absolve you from your responsibility or mitigate the risks to subjects that resulted from your failure to conduct Protocol **(b)(4)** under an active IND.

This letter is not intended to be an all-inclusive list of deficiencies with your clinical study of an investigational drug. It is your responsibility to ensure adherence to each requirement of the law and relevant FDA regulations. You should address these deficiencies and establish procedures to ensure that any ongoing or future studies will be in compliance with FDA regulations.

Within fifteen (15) working days of your receipt of this letter, you should notify this office in writing of the actions you have taken to prevent similar violations in the future. Failure to address the violations noted above adequately and promptly may result in regulatory action without further notice. If you believe you have complied with FDA regulations, include your reasoning and any supporting information for our consideration.

If you have any questions, please contact Douglas Pham at 301-796-1955; FAX 301-847-8748. Your written response and any pertinent documentation should be addressed to:

Douglas Pham, Pharm.D., J.D.  
Branch Chief (Acting)  
Compliance Enforcement Branch  
Division of Enforcement and Postmarketing Safety  
Office of Scientific Investigations  
Office of Compliance  
Center for Drug Evaluation and Research

Food and Drug Administration  
Building 51, Room 5348  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Sincerely yours,

*{See appended electronic signature page}*

David C. Burrow, Pharm.D., J.D.  
Office Director (Acting)  
Office of Scientific Investigations  
Office of Compliance  
Center for Drug Evaluation and Research  
U.S. Food and Drug Administration

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.  
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/s/

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DAVID C BURROW  
04/14/2016

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