Month xx, 2024

***(Choose either CDER or CBER address below and delete the other)***

U.S. Food and Drug Administration

Center for Drug Evaluation and Research (CDER)

Central Document Room

5901-B Ammendale Rd.

Beltsville, MD 20705-1266

*OR*

U. S. Food and Drug Administration

Center for Biologics Evaluation and Research (CBER)

Document Control Center

10903 New Hampshire Ave.

WO71, G112

Silver Spring, MD 20993-0002

CBERDCC\_eMailSub@fda.hhs.gov

**Subject: Request for IND Exemption**

Dear [Division Head]:

I am hereby submitting a request for an IND Exemption in accordance with 21 CFR 312.2 (b) and (e) and requesting exemption from the requirements of 21 CFR 312.23.

Disease or condition under investigation:

Investigational Product:

Investigational Product Formulation:

Modifications to the product Formulation: Yes/No (explain)

Investigational Product Manufacturer (and address):

We are requesting documentation of IND exemption from FDA and assert the following in support for our IND Exemption request:

1. XXX is lawfully marketed in the United States.
2. The proposed investigation is not intended to be reported to the FDA or any other Health Authority, by myself or a collaborator, as a well-controlled study in support of a new indication for the product or to support any other significant change in the labeling of the drug.
3. The proposed investigation is not intended to support a significant change in the advertising for the drug.
4. The proposed investigation does not involve a route of administration, dosage level, patient population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the product. See explanation below.
5. The proposed investigation will be conducted in compliance with the requirements for review by an IRB (21 CFR 56), CHOP Institutional Review Board, and with the requirements for informed consent set forth in 21 CFR parts 50.
6. The proposed investigation will be conducted in compliance with the requirements of 21 CFR 312.7 in that the investigation is not intended to promote or commercialize the drug product.

**Risk Rationale Explanation (#4)**

Route of Administration

Dosage Level

Patient Population

Other Factors

Summary

The proposed clinical protocol titled XXXX and current manufacturer’s labeling information is included with this submission for your review.

We look forward to your response. If you have any questions regarding this submission, or need any additional information, please do not hesitate to contact me directly at….(phone) (email) (address).

Sincerely,

[Your Name]

[Title]

Enclosures: Clinical study protocol

 Drug Label Information

Copy to: IND/IDE Support Program