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AOCG Memo No. 122-2023

BOC-09-38894

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MEMORANDUM

TO : ALL DISTRICT COLLECTORS
ALL SUB-PORT COLLECTORS
ALL OTHERS CONCERNED

FROM : 
ATTY. VENER S. BAQUIRAN -
Deputy Commissioner, AOCG

SUBJECT : INTERPOSING NO OBJECTION TO IMPORT INVESTIGATIONAL PRODUCTS AND SUPPLIES IN THE FORM OF USED AND EXPIRED PHARMACEUTICALS AND DRUGS COVERED BY CENTRAL DEPOT BUSINESS SET-UP WITH CONDITIONS

DATE : 13 March 2023

This is with reference to the attached letter reply dated 06 March 2023 addressed to Engr. Brigette Yves V. Cuevas, HSE Manager, **ZUELLIG PHARMA CORPORATION**, from Gilbert C. Gonzales, CESO III, Director and Concurrent Assistant Secretary for Field Operations, Environmental Management Bureau, Department of Environment and Natural Resources (**EMB-DENR**).

EMB-DENR noted that the said take back is part of the Central Depot Business Model that **ZUELLIG** had set-up where they will be able to facilitate the end-to-end supply chain solutions for clinical trials being conducted in different countries.

In this regard, EMB-DENR informs that they are interposing NO objection to the said request provided that following shall be complied with.

- a. Approval of EMB-DENR Office shall be secured for every importation of used and expired pharmaceuticals and drugs (**M503**) per country of export;
- b. M503 to be imported for destruction shall be included in ZUELLIG's inventory of hazardous waste (HW)
- c. Movement of the imported M503 from your warehouse to contracted TSD facility shall be covered by a Permit to Transport (**PTT**) obtain from the ONLINE HW Management System; and
- d. Applicable requirements and standards of DENR Administrative Order DAO No. 2013-22: *Revised Procedures and Standards for the Management of Hazardous Wastes (Revising DAO 2004-36)*, such as, but not limited to, **proper packaging and labeling, shall be enforced.**

For information and reference.

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MAR 21 2023

BY: Guindy TIME: 8:20

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ENGR. BRIGETTE YVES V. CUEVAS
HSE Manager
ZUELLIG PHARMA CORPORATION
Km. 14 West Service Road
South Superhighway cor. Edison Ave.
Sun Valley, Parañaque City
Email: bycuevas@zuelligpharma.com

MAR 06 2023

SUBJECT: INTERPOSING NO OBJECTION TO IMPORT INVESTIGATIONAL PRODUCTS AND SUPPLIES IN THE FORM OF USED AND EXPIRED PHARMACEUTICALS AND DRUGS COVERED BY CENTRAL DEPOT BUSINESS MODEL SET-UP WITH CONDITIONS

Dear Engr. Cuevas:


This has reference to your letter (IIS Transaction No.: CO-2022-041312) dated 18 October 2022 requesting reconsideration on your intent to take back investigational products and supplies in the form of used, unused, or expired pharmaceuticals and drugs generated from your clinical trial activities outside the Philippines for eventual destruction. It is noted that the said take back is part of the Central Depot Business Model that you had set-up where you will be able to facilitate the end-to-end supply chain solutions for clinical trials being conducted in different countries.

In this regard, please be informed that we interpose no objection to the said request provided that the following shall be complied with:

1. An approval shall be secured from this Office for every importation of used and expired pharmaceuticals and drugs (M503) per country of export;
2. M503 to be imported for destruction shall be included in your inventory of hazardous wastes (HW);
3. Movement of the imported M503 from your warehouse to contracted TSD facility shall be covered by a Permit to Transport (PTT) obtained from the Online HW Management System; and
4. Applicable requirements and standards of DENR Administrative Order (DAO) No. 2013-22: *Revised Procedures and Standards for the Management of Hazardous Wastes (Revising DAO 2004-36)*, such as, but not limited to, proper packaging and labeling, shall be enforced.

We hope we have addressed your concern.

Very truly yours,


GILBERT C. GONZALES, CESO III
Director and concurrent
Assistant Secretary for Field Operations

cc: **The Commissioner**
Bureau of Customs
Port Area, Manila

