DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
United States Food and Drug Administration 12420 Parklawn Dr., Room 2032 Rockville, MD 20857 ORAPHARMinternational483responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	09/05/2023-09/07/2023
	FEI NUMBER 3015685285

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Yang Zhigang, General Manager Assistant

FIRM NAME	STREET ADDRESS
Zhejiang Peptides Biotech Co., Ltd	No. 8 Hengyizhi Road, Sanjie Town, Shengzhou City
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Shaoxing, Zhejiang, CN, 312452	API Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Your firm has not established and implemented adequate quality control for highly sensitizing materials

The following workshop(b) (4) is used to manufacturer(b) (4) active pharmaceutical ingredients. However, your firm does not have control to prevent, detect and control cross contamination in the manufacturing workshop. For example:

a.) Your firm does not follow your process validation program. In addition, you do not have process validation for (b) (4) active pharmaceutical ingredient. In addition, this product has been shipped to the USA market.
b.) Your firm's manufacturing batch records doesn't identify the manufacturing workshops for(b) (4) In addition, two of your employees could not come to a consensus about the location for the manufacturing workshop.
c.) Your cleaning validation procedure and risk assessment is not validated and adequately sound because your firm could not ensure that cross contamination in manufacturing workshops

OBSERVATION 2

Your firm does not monitor utilities such as(b) (4)

Specifically, SOP-QA-QA007, "Product Quality Review Management Procedure", effective date: 12/17/2022, states that there should be(b) (4) testing performed for utilities systems which include(b) (4) and (b) (4) However, your firm does not have(b) (4) reports from 2019-2021 for(b) (4) which is used in the manufacturing for active pharmaceutical ingredients.

OBSERVATION 3

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Tonia Bernard, CSO	Tonia Bernard, CSO	09/08/23

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Your firm lacks a scientifically sound cleaning validation program for the active pharmaceutical ingredient Specifically,

You completed the cleaning validation risk assessment for workshop (b) (4) in 2022. However, you did not evaluate the most difficult to clean and highest risk product manufactured in the workshop. In addition, this workshop uses shared non-dedicated equipment to manufacture (b) (4) active pharmaceutical ingredients.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
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