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

Beijing Shunxin Meihua Bio-technical Co., Ltd. 9/

Department of Health and Human Services

Public Health Se
Food and Drug A
Silver Spring, M

Warning Letter

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 29, 2014

Mr. Qing Long Ge
General Manager
Beijing Shunxin Meihua Bio-technical Co., Ltd
Bei Fa Xin Duan
No. 7 Fuqian Road
Daxingqu, Shunyi District
Beijing 101300
China

Dear Mr. Ge:

On February 19, 2014, the U.S. Food and Drug Administration (FDA), arrived at your drug manufacturing facility, Beijing Shunxin M Bei Fa Xin Duan, No. 7 Fuqian Road, Daxingqu, Shunyi District, Beijing, China, to conduct an inspection. The FDA investigators d refused an FDA inspection. Under the Food and Drug Administration Safety and Innovation Act (FDASIA), Section 707, your drugs Section 501(j) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 351(j), in that they have been manufactured, proce establishment where the owner or operator has limited inspection and/or refused inspection.

Your firm limited an inspection and/or refused to permit the FDA inspection as follows:

1. Your site produces crude heparin for purification into finished API. On February 19, 2014, FDA investigators explained the purp responsible official at Beijing Shunxin Meihua Bio-technical Co., Ltd, (hereafter Shunxin). You barred the investigators access to th manufacturing facility. In several instances, the investigators requested to inspect the facility, but were repeatedly denied access to limited FDA access to certain requested records. For example, the FDA investigators requested batch production records for reviev records repeatedly.

Furthermore, during the review of a list of your suppliers, one of the few documents you did provide, we noted that you are supplied the same physical address as, and is thus an alias of, the **(b)(4)**, a firm that is currently on FDA Import Alert 55-03, "Detention Witho Forms of Heparin and Heparin-Related Products." This Import Alert can be found on the FDA public website:

http://www.accessdata.fda.gov/cms_ia/importalert_821.html (http://www.accessdata.fda.gov/cms_ia/importalert_821.html)

Import Alert 55-03 includes firms for which there is information indicating that their heparin and/or heparin-related products appear t
detention without physical examination under Import Alert 55-03 is that the firm's quality system is inadequate for the prevention of
chondroitin sulfate (OSCS))or otherwise does not conform with CGMP. If your firm is being directly or indirectly supplied by establis
historical OSCS contamination or that otherwise lack adequate CGMP, your firm could be manufacturing heparin and heparin-relate
alert. FDA recommends that you ensure that you properly evaluate and qualify all your suppliers (e.g., suppliers of crude heparin o
and change the source of your supply, where appropriate. Consequently, your use of this supplier on Import Alert 55-03 led to the
heparin drugs.

We also note that FDA test results confirmed the presence of ruminant DNA in one of two samples of porcine crude heparin produc
facility of one of your customers in China. The sample containing the ruminant DNA came from your crude heparin batch BB12042
these positive results is available at the following website:

**http://www.fda.gov/AnimalVeterinary/ScienceResearch/ToolsResources/ucm350289.htm
(http://www.fda.gov/AnimalVeterinary/ScienceResearch/ToolsResources/ucm350289.htm)**.

For further reference regarding ruminant DNA in heparin, please also see the guidance "Guidance for Industry: Heparin for Drug an
Crude Heparin for Quality" that can be found at the following website:

**http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291390.pdf
(http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291390.pdf)**.

Your firm was placed on Import Alert 55-03, Import Alert 66-40, and Import Alert 99-32 on July 22, 2014.

The violation cited in this letter is not intended to be an all-inclusive list of violations that exist at your facility. You are responsible fo
causes of the violation identified above and for preventing their recurrence and the occurrence of other violations.

Until FDA is permitted to inspect your facility and confirms compliance with CGMP, this office may recommend withholding approva
supplements listing your firm as a drug manufacturer. In addition, shipments of articles manufactured at Beijing Shunxin Meihua Bio
the United States are subject to refusal of admission pursuant to Section 801(a)(3) of the Act, 21 U.S.C. 381(a)(3).

Please submit any written response within fifteen working days of receipt of this letter.

Please identify your response with FEI # 3010657600.

Please send your reply to:
Mary D. Davis-López
Compliance Officer
U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Office of Manufacturing and Product Quality
Division of International Drug Quality
White Oak, Building 51
10903 New Hampshire Ave
Silver Spring, MD 20993
Tel: (301) 796-8859
Fax: (301) 847-8741

Sincerely,
/S/
Thomas J. Cosgrove, J.D.
Acting Director
Office of Manufacturing and Product Quality
Office of Compliance
Center for Drug Evaluation and Research