U.S. Food & Drug Administration

Import Alert 66-76

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(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public).

Import Alert # 66-76
Published Date: 01/05/2017
Type: DWPE
Import Alert Name:

"Detention Without Physical Examination of Drugs or Active Pharmaceutical Ingredients from Facilities that have not submitted self-identifying information or paid facility fees required under GDUFA"

Reason for Alert:

This Import Alert identifies certain facilities that are not in compliance with the following fee payment and self-identification requirements of the Generic Drug User Fee Amendments of 2012 (GDUFA). The facility is a specific business or other entity whose owner is subject to self-identification or fee payment. Any drug manufactured by the facility that is not subject to this Import Alert will be identified as exempted.

In GDUFA, Congress authorized FDA to assess fees for facilities identified, or intended to be identified, in approved or pending generic drug submissions, including abbreviated new drug applications (ANDAs) and any amendments or prior approval supplements to ANDAs, for dedicated use in FDA's human generic drug activities (21 U.S.C Section 379j-41 & 21 U.S.C Section 379j-42). Pursuant to GDUFA, FDA assesses an annual facility fee upon the facility owner. If, as of the facility due date, a facility is identified or intended to be identified in a pending or approved generic drug submission to produce one or more finished dosage forms of a human generic drug, the person that owns that facility must pay an annual facility fee (21 U.S.C. Section 379j-42(a)(4)). The fees for fiscal year 2013 were due on March 4, 2013 (21 U.S.C. Section 379j-42(a)(4)(D)(i); 78 FR 3900 (Jan. 17, 2013)). The fees for fiscal year 2014 were due October 18, 2013 (21 U.S.C. Section 379j-42(a)(4)(D)(ii)). The fees for fiscal year 2015 were due on October 1, 2014. (21 U.S.C. Section 379j-42(a)(4)(D)(ii); 79 FR 44797 (Aug. 1, 2014). The fees for fiscal years 2016 through 2017 are due on the later of the first business day on or after October 1 of each year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of GDUFA fees for such year (21 U.S.C. Section 379j-42(a)(4)(D)(ii)). Facilities that solely produce positron emission tomography drugs are exempt from the facility fee requirement (21 U.S.C. Section 379j-42(l)).

In addition, GDUFA defines a facility in relevant part as "a business or other entity ... at one geographic location or address engaged in manufacturing or processing an active pharmaceutical ingredient or a finished dosage form" (21 U.S.C. Section 379j-41(5)(A)(i)(II)). If such a facility is identified or intended to be identified in a pending or approved generic drug submission to produce a finished dosage form of a human generic drug or an active pharmaceutical ingredient contained in a human generic drug, the person that owns that facility must submit information concerning the facility to FDA (self-identify) each year in accordance with 21 U.S.C. Section 379j-42(f). Self-identification for fiscal year 2013 was required on or before December 3, 2012 (21 U.S.C. Section 379j-42(f)(2)(A); 77 FR 60125 (Oct. 2, 2012)). Self-identification for fiscal year 2014 was required between May 1, 2013 and June 1, 2013 (21 U.S.C. Section 379j-42(f)(2)(B); 78 FR 22553 (Apr. 16, 2013)). Self-identification for fiscal years 2015 through 2017 is required before June 1 of the previous fiscal year (21 U.S.C. Section 379j-42(f)(2)(B)).

Section 502(aa) of the Federal Food, Drug, and Cosmetic Act (�Act') provides that any drug or active pharmaceutical ingredient manufactured, prepared, propagated, compounded, or processed in a facility for which required facility fees have not been paid or required self-identifying information has not been submitted, or any drug containing an active pharmaceutical ingredient manufactured, prepared, propagated, compounded, or processed in such a facility, are deemed to be misbranded (21 U.S.C. Section 352(aa) and 21 U.S.C. Section 379j-42(g)(4)(A)(iii)). In addition, Section 801(a)(3) of the Act provides that drugs that appear to be misbranded may be subject to refusal of admission to the United States. (21 U.S.C. Section 381(a)(3)).

The Red List of this Import Alert identifies certain facilities whose owners are not in compliance with the fee payment or self-identification requirements of GDUFA and that have imported or offered for import drugs or active pharmaceutical ingredients. The owners of the facilities identified below were notified individually and in writing, by warning letter and/or other means, that they are in violation of the Act and their articles are subject to refusal of admission because they appear to be misbranded. FDA may also have placed the facilities on a publicly available arrears list posted at http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM346165.pdf. The owners of these facilities have not made significant efforts to correct the violations during the time allotted in the communication notifying them of the violation.

Guidance:

Districts may detain, without physical examination, the indicated products from the facilities identified on the Red List of this Import Alert.

In order to secure release of an individual shipment subject to detention without physical examination (DWPE) under this Import Alert, the owner, consignee, and/or another responsible party to the shipment should provide evidence indicating the owner of the subject facility is in full compliance with the fee payment and self-identification requirements of GDUFA.

In order to remove a shipment from DWPE, information should be provided to FDA to adequately demonstrate that the owner of the facility has resolved the conditions that gave rise to the appearance of the violation, so that the agency will have confidence that future import entries will be in compliance. This may include a letter detailing its corrective actions, accompanied by documentation.

For guidance on removal from DWPE, refer to FDA's Regulatory Procedures Manual, Chapter 9, "Detention Without Physical Examination (DWPE)."

A facility owner, shipper, or importer may request removal from import alert by forwarding information supporting the request to FDA at the following address:

Food and Drug Administration
Division of Import Operations
12420 Parklawn Drive, ELEM-3109
Rockville, MD 20857

Or via email: Importalerts2@fda.hhs.gov

Requests for removal from DWPE will be reviewed by the Division of Import Operations (DIO) and then referred to the Center for Drug Evaluation and Research (CDER) for additional evaluation.

For questions or issues concerning import operations, contact DIO Import Operations and Maintenance Branch at (301) 796-0356.

Questions concerning fee payment requirements can be directed to CDERCollections@fda.hhs.gov or to askgdufa@fda.hhs.gov and questions concerning self-identification requirements can be directed to askgdufa@fda.hhs.gov.

Product Description:

Various Drugs and Drug Products

Charge:

"The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be misbranded as defined in section 502(aa) of the Act. It appears the drug or active pharmaceutical ingredient was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required in 21 U.S.C. Section 379j-42(a)(4), or it contains an active pharmaceutical ingredient that was manufactured, prepared, propagated, compounded, or processed in such a facility. [Misbranding, Section 502(aa), 801(a)(3)]"

OASIS charge code GDUFA FEE

and

"The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be misbranded as defined in section 502(aa) of the Act. It appears that the drug or active pharmaceutical ingredient was manufactured, prepared, propagated, compounded, or processed in a facility for which identifying information required by 21 U.S.C. Section 379j-42(f) has not been submitted, or it contains an active pharmaceutical ingredient that was manufactured, prepared, propagated, compounded, or processed in such a facility.[Misbranding, Section 502(aa), 801(a)(3)]"

OASIS charge code GDUFA SELF

List of firms and their products subject to Detention without Physical Examination (DWPE) under this Import Alert (a.k.a. Red List)

CHINA

Jiangsu ZW Pharmaceuticals Co. Ltd. **Date Published : 07/13/2016**
1518 Longjiang (N) Road , Binjiang Ind. Park, Xinbei District , Changzhou City, Jiangsu Province CHINA

55 - - - -- Pharm Necess & Ctnr For Drug/Bio — Date Published: 07/13/2016
Notes:All Drug & Drug Products

56 - - - -- Antibiotics (Human/Animal) — Date Published: 07/13/2016
Notes:All Drug & Drug Products

60 - - - -- Human and Animal Drugs — Date Published: 07/13/2016
Notes:All Drug & Drug Products

61 - - - -- Human and Animal Drugs — Date Published: 07/13/2016
Notes:All Drug & Drug Products

62 - - - -- Human and Animal Drugs — Date Published: 07/13/2016
Notes:All Drug & Drug Products

63 - - - -- Human and Animal Drugs — Date Published: 07/13/2016
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Notes:All Drug & Drug Products

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Notes:All Drug & Drug Products

66 - - - -- Human and Animal Drugs — Date Published: 07/13/2016
Notes:All Drug & Drug Products

Wuxi Kaili Pharmaceutical Company LTD. **Date Published : 07/13/2016**
1 Penggan Village, Zhoutie , Yixing City, Jiangsu CHINA

55 - - - -- Pharm Necess & Ctnr For Drug/Bio Date Published: 07/13/2016
Notes:All Drug & Drug Products

56 - - - -- Antibiotics (Human/Animal) Date Published: 07/13/2016
Notes:All Drug & Drug Products

60 - - - -- Human and Animal Drugs Date Published: 07/13/2016
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65 - - - -- Human and Animal Drugs Date Published: 07/13/2016
Notes:All Drug & Drug Products

66 - - - -- Human and Animal Drugs Date Published: 07/13/2016
Notes:All Drug & Drug Products

INDIA

Sharon Bio-Medicine Limited **Date Published : 07/13/2016**
1027/28/30/37 Khasra No , Central Hope Town, Uttarakhand INDIA

55 - - - -- Pharm Necess & Ctnr For Drug/Bio Date Published: 07/13/2016
Notes:All Drug & Drug Products

56 - - - -- Antibiotics (Human/Animal) Date Published: 07/13/2016
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