# Import Alert 55-05



*(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** # 55-05
**Published Date:** 03/27/2018
**Type:** DWPE

## Import Alert Name:

DETENTION WITHOUT PHYSICAL EXAMINATION OF FINISHED DOSAGE DRUG PRODUCTS, ACTIVE PHARMACEUTICAL INGREDIENTS AND INACTIVE INGREDIENTS FOR POTENTIALLY HAZARDOUS MICROBIOLOGICAL CONTAMINATION

## Reason for Alert:

Due to similar issues, the information in IA #55-04 is being incorporated into this alert and will henceforth be discontinued.

FDA collects and analyzes samples of finished dosage products, active pharmaceutical ingredients and inactive ingredients considered at risk for potentially hazardous microbial contamination that pose a health risk. Detention without physical examination may be appropriate when sample results reveal a potential health risk.

## Guidance:

Districts may detain, without physical examination, the specified

products from the firms listed in the Red List of this Import Alert.

Districts should recommend detention without physical examination under this import alert when analytical results reveal the presence of potentially hazardous microbial contamination for pharmaceutical use. Forward background information, including analytical worksheets, product labeling and entry documents, to the Division of Import Operations (DIO). DIO will coordinate with CDER for concurrence.

In order for a firm to be removed from detention without physical examination, information should be provided to FDA to adequately demonstrate that the manufacturer has resolved the conditions that gave rise to the appearance of the violation, so that the agency will have confidence that future entries will be in compliance. This may include a letter detailing its corrective actions, accompanied by documentation.

For guidance on removal from detention without physical examination,

refer to FDA□s Regulatory Procedures Manual, Chapter 9, "Detention

Without Physical Examination (DWPE)."

If a firm, shipper or importer wishes to request removal from detention without physical examination, they should forward information supporting their 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

For questions or issues involving import operations, contact the Division of Import Operations at (301) 796-0356.

For questions or issues concerning science, science policy, analysis, preparation, or analytical methodology, contact the Office of Regulatory Science at (301) 796-6600.

## Product Description:

CDER regulated finished dosage form drug products, active pharmaceutical ingredients, and inactive ingredients

## Charge:

The article is subject to refusal of admission pursuant to section 801(a)(3) of the FFD&CA in that the article contains potentially hazardous, or otherwise objectionable in light of intended use, microbial adulteration and therefore consists in part of a filthy substance. [Adulteration, Section 501(a)(1)].

OASIS CHARGE CODE: FILTH

AND/OR

The article is subject to refusal of admission pursuant to section 801(a)(1) in that the article appears to have been manufactured, processed, or packed under insanitary conditions

OASIS CHARGE CODE: MFR INSAN

AND/OR

The article is subject to refusal of admission pursuant to section 801(a)(3) in that the article appears to have been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health [Adulteration, Section 501(a)(2)(A)].

OASIS CHARGE CODE: INSANITARY

AND/OR

The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or holding of the article do not appear to conform to or are not operated or administered in conformity with current

good manufacturing practices. [Adulteration, Section 501(a)(2)(B)].

OASIS CHARGE CODE: DRUG GMPs

PROBLEM: Adulteration

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

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**CANADA**

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**Delta Pharma Inc.** **Date Published : 05/22/2013**
1655 Rte Transcanadienne , Dorval, Quebec CANADA
*66 V - - 99* Miscellaneous Patent Medicines, Etc. Date Published: 05/22/2013
Desc: Face Values for Baby Healing Ointment

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**INDIA**

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**Contacare Ophthalmics & Diagnostics** **Date Published : 08/23/2017**
310b Village Sim , Block No , Dabhasa, Gujarat INDIA
*55 R P - 14* Hydroxypropyl Methylcellulose (Pharmaceutic Necessity - Suspending Agent), Pharma Necess Date Published: 08/23/2017
Desc: Hydroxypropyl Methyl Cellulose
Notes: DWPE applies to all aseptically processed drugs manufactured or shipped by Contacare Ophthalmics & Diagnostics.
*55 R P - 55* Sodium Chloride (Pharmaceutic Necessity - Tonicity Agent), Pharma Necess Date Published: 08/23/2017
Desc: Sodium Chloride
Notes: DWPE applies to all aseptically processed drugs manufactured or shipped by Contacare Ophthalmics & Diagnostics.
*63 X C P 69* Iopydol (Diagnostic Aid) (Drugs), Human - Rx/Single Ingredient, Small Volume Parenteral <100ml
Date Published: 08/23/2017
Desc: Lopydol
Notes: DWPE applies to all aseptically processed drugs manufactured or shipped by Contacare Ophthalmics & Diagnostics.
*63 X - - 12* Fluorescein Sodium (Diagnostic Aid) (Drugs) Date Published: 08/23/2017
Desc: Fluorescein Sodium
Notes: DWPE applies to all aseptically processed drugs manufactured or shipped by Contacare Ophthalmics & Diagnostics.
*63 X - - 99* Diagostic Aid (Drugs) N.E.C. Date Published: 08/23/2017

Desc: Sodium Chloride
Notes: DWPE applies to all aseptically processed drugs manufactured or shipped by Contacare Ophthalmics & Diagnostics.
*65 R A K 19* Sodium Chloride (Replenisher), Human - Non/Rx Single Ingredient, Sterile Liquid Date Published: 08/23/2017
Desc: Sodium Chloride
Notes: DWPE applies to all aseptically processed drugs manufactured or shipped by Contacare Ophthalmics & Diagnostics.

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## KOREA, REPUBLIC OF (SOUTH)

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**Neo Vision Co., Ltd.** **Date Published : 12/13/2016**
93 Jeungsin-ro , Iceon-si, Gyeonggi-do KOREA, REPUBLIC OF (SOUTH)
*55 - - - --* Pharm Necess & Ctnr For Drug/Bio Date Published: 12/13/2016
Notes: All drugs and drug products
*56 - - - --* Antibiotics (Human/Animal) Date Published: 12/13/2016
Notes: All drugs and drug products
*60 - - - --* Human and Animal Drugs Date Published: 12/13/2016
Notes: All drugs and drug products
*61 - - - --* Human and Animal Drugs Date Published: 12/13/2016
Notes: All drugs and drug products
*62 - - - --* Human and Animal Drugs Date Published: 12/13/2016
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*63 - - - --* Human and Animal Drugs Date Published: 12/13/2016
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*66 - - - --* Human and Animal Drugs Date Published: 12/13/2016
Notes: All drugs and drug products

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## MEXICO

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**Brady Mexico S De RL de CV** **Date Published : 08/26/2016**
Guerrero Negro , Tijuana, Bc MEXICO
*55 R - - 55* Sodium Chloride (Pharmaceutic Necessity - Tonicity Agent) Date Published: 08/26/2016
Desc: Eyesaline Eyewash
Notes:

*55 R - - 56* Ethyl Oleate (Pharmaceutic Necessity - Vehicle) Date Published: 08/26/2016
Desc: Eyesaline Eyewash
Notes:

*65 F - - 06* Water, Purified (Eyewash) Date Published: 08/26/2016
Desc: Eyesaline Eyewash
Notes:

*65 R - - 12* Potassic Saline (Injection) (Replenisher) Date Published: 08/26/2016
Desc: Eyesaline Eyewash
Notes:

**Industria Farmaceutica Andromaco S.A. de C.V.** **Date Published : 03/27/2018**
Calle Eje 3 Norte No. 202 , Parque Industrial Toluca 2000 , Toluca, Mexico MEXICO
*55 - - - --* Pharm Necess & Ctnr For Drug/Bio Date Published: 03/27/2018

Notes: All Drug and Drug Products; A shipment of "Pasta de Lassar Andr&#65533;maco" Zinc Oxide (Skin Protectant) Diaper Rash Cream was found to contain potentially hazardous microbiological contamination. CDER recommends to place Industria Farmaceutica Andromaco S.A. de C.V. and all drug products manufactured by this firm on the Red List of IA #55-05 to protect the public health.

*56 - - - --* Antibiotics (Human/Animal) Date Published: 03/27/2018

Notes: All Drug and Drug Products; A shipment of "Pasta de Lassar Andr&#65533;maco" Zinc Oxide (Skin Protectant) Diaper Rash Cream was found to contain potentially hazardous microbiological contamination. CDER recommends to place Industria Farmaceutica Andromaco S.A. de C.V. and all drug products manufactured by this firm on the Red List of IA #55-05 to protect the public health.

*60 - - - --* Human and Animal Drugs Date Published: 03/27/2018

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*61 - - - --* Human and Animal Drugs Date Published: 03/27/2018

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*62 - - - --* Human and Animal Drugs Date Published: 03/27/2018

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*63 - - - --* Human and Animal Drugs Date Published: 03/27/2018

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*64 - - - --* Human and Animal Drugs Date Published: 03/27/2018

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*65 - - - --* Human and Animal Drugs Date Published: 03/27/2018

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*66 - - - --* Human and Animal Drugs Date Published: 03/27/2018

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**UNITED STATES**

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**Sperian Eye & Face Protection, Inc** **Date Published : 08/26/2016**

825 E Business Highway 151 , Platteville, WI 53818-3763 UNITED STATES

*55 R - - 55* Sodium Chloride (Pharmaceutic Necessity - Tonicity Agent) Date Published: 08/26/2016

Desc: Eyesaline Eyewash

*55 R - - 56* Ethyl Oleate (Pharmaceutic Necessity - Vehicle) Date Published: 08/26/2016

Desc: Eyesaline Eyewash

*65 F - - 06* Water, Purified (Eyewash) Date Published: 08/26/2016

Desc: Eyesaline Eyewash

*65 R - - 12* Potassic Saline (Injection) (Replenisher) Date Published: 08/26/2016

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