Taro Pharmaceuticals U.S.A., Inc

URGENT: VOLUNTARY MARKET WITHDRAWAL
Ibuprofen Oral Suspension USP, 100 mg/5 mL

November 11, 2019

Dear Valued Customer,

This is to notify you that Taro Pharmaceuticals U.S.A. is conducting a Voluntary Market Withdrawal to the **Retail Level** for 89 lots of Ibuprofen Oral Suspension USP, 100 mg/5 mL. Taro initiated a voluntary market withdrawal to the wholesale level on September 27, 2019, and now Taro is extending the withdrawal to the **Retail Level** based on FDA classification. Taro is withdrawing these lots from further distribution as a precautionary measure due to an extremely small risk that some small particles of an inert plastic material could have been introduced to the product during the empty bottle air-cleaning process.

Currently, all distributed lots of Taro Ibuprofen Oral Suspension USP, 100 mg/5 mL meet all of the established product specifications, and no adverse health consequences are expected with continued use of these products.

The products subject to this market action are listed by NDC number in the table below, and the individual lot numbers are listed on page 2 of the attached Recall Response Form.

NDC	Product Name	Size	Expiration Dates of Affected Lots
51672-1385-8	Ibuprofen Oral Suspension USP, 100 mg/5 mL	4 oz.	All lots with expiration dates from: Sept. 2019 through Mar. 2021
51672-1385-9	Ibuprofen Oral Suspension USP, 100 mg/5 mL	16 oz.	
51672-2130-8	Ibuprofen Oral Suspension USP, 100 mg/5 mL Children's (OTC) Berry Flavor, Dye-Free	4 oz.	
51672-2130-1	Ibuprofen Oral Suspension USP, 100 mg/5 mL Children's (OTC) Berry Flavor, Dye-Free	8 oz.	

Please examine your inventory **immediately** to determine if you have any units of the Ibuprofen Oral Suspension USP, 100 mg/5 mL listed on page 2 of the response form. If so, please **discontinue distributing these lots** and promptly return all units to our distribution center according to the following instructions:

(1) Please fill out the attached Recall Response Form completely

(2) Return the completed form via Fax to **914-470-4946** ..... or mail the completed form to:

Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive
Hawthorne, New York 10532
Attention: Richard Lewellyn

(3) Taro will provide return authorization/call tag to ship any returned merchandise to our distribution center at:

Taro Pharmaceuticals U.S.A., Inc.
1 Commerce Drive
Cranbury, New Jersey 08512
Attn: RETURNED GOODS - WITHDRAWAL - Ibuprofen Oral Suspension USP, 100 mg/5 mL

NOTE: Please return the form even if you do not have any inventory of the impacted lots.

3 Skyline Drive, Hawthorne, NY 10532 Tel: 914-345-9001 1-888-TARO-USA Fax: 914-345-8728 www.taro.com

Taro apologizes for any inconvenience this may have caused. We appreciate your prompt attention in looking through your inventory, discontinuing distribution of the affected lots and returning all units. If you have any questions about the content of this letter, please contact Richard Lewellyn at 1-800-544-1449 ext. 6334 or via email to richard.lewellyn@taro.com, or me at 914-345-9001 ext. 6216.

Sincerely,

Scott P. Keenan

Scott Keenan
Manager, Quality Compliance

Enclosure: Recall Response Form – Ibuprofen Oral Suspension

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Recall Response Form – Taro Ibuprofen Oral Suspension
November 2019 **Page 1 of 2**

Taro Pharmaceuticals U.S.A., Inc.

This response form is for retail withdrawal of Ibuprofen Oral Suspension USP, 100 mg/5 mL, 4 oz., 8 oz. and 16 oz. containers by Taro Pharmaceuticals U.S.A., Inc. Please provide the information requested below and return the form to Taro whether or not you have any inventory of the IMPACTED PRODUCTS LISTED ON PAGE 2.

Please enter the following information, completely:

Pharmacy/Retailer

Name of Business: _____ Phone: _____

Address: _____

_____

Wholesale Supplier/Distributor

Name: _____ Phone: _____

Address/Location: _____

Wholesaler/Distributor Account Number: _____

Please review the list of product lots on page 2 which are subject to this market action, and indicate the quantity of any lots that you have on hand in the boxes next to each lot number.

Check all that apply:

- ☐ I have read and understood the instructions provided in the withdrawal letter
- ☐ I have checked my stock for any inventory of the product lots listed on **PAGE 2** of this form
- ☐ **Check here IF YOU DO NOT have any inventory,** and please return this form
- ☐ Check here if you **DO** have inventory of any of the impacted lots listed on **PAGE 2** of this form

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Please FAX the completed response form to Richard Lewellyn at: 914-470-4946

...or return the form BY MAIL to: Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive
Hawthorne, New York 10532
Attention: Richard Lewellyn

A call tag will be issued to you for any returned merchandise, once Taro receives the response form

(Note: Please include a copy of this form with your return shipment and provide the Return Authorization Number)

Recall Response Form – Taro Ibuprofen Oral Suspension
November 2019

Taro Pharmaceuticals U.S.A., Inc.

If you have any inventory of the lots listed below, please enter the quantities in the tables

NDC 51672-2130-8 4 oz. bottles

Lot #	Expiration	Quantity
A972934375	Dec-2020	
A973034375	Dec-2020	
E875131667	Apr-2020	
E875231667	Apr-2020	
J871033189	Sep-2020	
J871133189	Sep-2020	

NDC 51672-1385-8 4 oz. bottles

Lot #	Expiration	Quantity
A973134376	Dec-2020	
D873031376	Mar-2020	
D967635229	Mar-2021	
J871233188	Sep-2020	
K779030125	Oct-2019	
L866934047	Nov-2020	

NDC 51672-2130-1 8 oz. bottles

Lot #	Expiration	Quantity
J871033187	Sep-2020	

NDC 51672-1385-9 16 oz. bottles

Lot #	Expiration	Quantity
A887230568	Dec-2019	
A887330568	Dec-2019	
A887430568	Dec-2019	
A973134748	Dec-2020	
A973234423	Dec-2020	
A973334424	Dec-2020	
A979534425	Dec-2020	
A979634426	Dec-2020	
A979734427	Dec-2020	
A979834428	Dec-2020	
B865430568	Jan-2020	
B865530568	Jan-2020	
B865630568	Jan-2020	
B869530568	Jan-2020	
B869630568	Jan-2020	
B974034749	Jan-2021	
B974134750	Jan-2021	
B974234751	Jan-2021	
B974334752	Jan-2021	
B974434753	Jan-2021	
D866431198	Mar-2020	
D866531198	Mar-2020	
D866631198	Mar-2020	
D866731198	Mar-2020	
D866831198	Mar-2020	
D866931198	Mar-2020	
D872631198	Mar-2020	
D872731198	Mar-2020	
D872831198	Mar-2020	
D872931198	Mar-2020	
D873031834	Mar-2020	
E875331834	Apr-2020	
E875431834	Apr-2020	
E883831834	Apr-2020	
E883931834	Apr-2020	
E884031834	Apr-2020	
E884131834	Apr-2020	
F865131834	May-2020	

NDC 51672-1385-9 16 oz. bottles

Lot #	Expiration	Quantity
G879432436	Jun-2020	
G879532436	Jun-2020	
G879632436	Jun-2020	
G879732436	Jun-2020	
G879832436	Jun-2020	
G879932436	Jun-2020	
G881632436	Jun-2020	
G882232436	Jun-2020	
H865232436	Jul-2020	
H865332436	Jul-2020	
H870832436	Jul-2020	
I885233156	Aug-2020	
I885333156	Aug-2020	
I885433156	Aug-2020	
I885533156	Aug-2020	
I885633156	Aug-2020	
I885733164	Aug-2020	
J784029698	Sep-2019	
J784129698	Sep-2019	
J868533164	Sep-2020	
J868633164	Sep-2020	
J868733164	Sep-2020	
J868833164	Sep-2020	
J868933164	Sep-2020	
J869033164	Sep-2020	
K765129698	Oct-2019	
K765229698	Oct-2019	
K765329698	Oct-2019	
K769329698	Oct-2019	
K778829698	Oct-2019	
K778929698	Oct-2019	
L866434042	Nov-2020	
L866534043	Nov-2020	
L866634044	Nov-2020	
L866734045	Nov-2020	
L866834046	Nov-2020	
L866934422	Nov-2020	

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