



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



05 OCT 2016

FDA ADVISORY
No. **2016-111**

TO: THE GENERAL PUBLIC, ALL HEALTHCARE PROFESSIONALS, AND THE OFFICERS OF THE FIELD REGULATORY OPERATIONS OFFICE

SUBJECT: Product Recall of All Lots of Solid and Liquid Preparations Manufactured by Accord Bio Laboratories from 31 October 2014 up to 27 October 2015

The general public and all healthcare professionals are hereby warned by the Food and Drug Administration (FDA) about lots of the following solid and liquid preparations manufactured by Accord Bio Laboratories located at #54 Belen St., Brgy. Gulod, Novaliches, Quezon City which were produced from 31 October 2014 up to 27 October 2015:

#	PRODUCT NAME	REG. NO.	LOT NO.	MFG. DATE	EXP. DATE
1	Vitamin B Complex + Vitamin C + Ferrous Sulfate Capsule (Imefer)	DRP-296	135124	Nov 2014	Nov 2016
			136124	Dec 2014	Dec 2016
			140124	Dec 2014	Dec 2016
			108125	Feb 2015	Feb 2017
			110125	Mar 2015	Mar 2017
			111125	Mar 2015	Mar 2017
			118125	Jun 2015	Jun 2017
			122125	Jun 2015	Jun 2017
			125125	Jul 2015	Jul 2017
			126125	Jul 2015	Jul 2017
			133125	Aug 2015	Aug 2017
			135125	Sep 2015	Sep 2017
			141125	Oct 2015	Oct 2017
			142125	Oct 2015	Oct 2017
			144125	Oct 2015	Oct 2017
			147125	Oct 2015	Oct 2017
			148125	Oct 2015	Oct 2017
2	Carbocysteine 500 mg Capsule (Aflem)	HRP-015	102015	Jan 2015	Jan 2017
			117015	May 2015	May 2017
3	Multivitamins + Minerals Capsule (Cuteplex)	DR-XY7439	115115	May 2015	May 2017
4	Bromhexine Hydrochloride 8 mg Capsule (Muconix)	DR-XY33911	139184	Dec 2014	Dec 2016
			134185	Sep 2015	Sep 2017

5	Thiamine HCl (Vitamin B1) + Pyridoxine HCl (Vitamin B6) + Cyanocobalamin (Vitamin B12) 300 mg/100 mg/100 mcg Capsule (Nervilan)	DRP-295	137254	Dec 2014	Dec 2016
			138254	Dec 2014	Dec 2016
			101255	Jan 2015	Jan 2017
			106255	Feb 2015	Feb 2017
			112255	Mar 2015	Mar 2017
			113255		
			119255	Jun 2015	Jun 2017
			121255		
			123255	Jul 2015	Jul 2017
			124255		
			131255	Aug 2015	Aug 2017
			137255	Sep 2015	Sep 2017
			138255		
			143255	Oct 2015	Oct 2017
			145255		
6	Mefenamic Acid 500 mg Capsule (Metaflam)	DRP-680	105155	Jan 2015	Jan 2017
			116155	May 2015	May 2017
			139155	Oct 2015	Oct 2017
7	Mefenamic Acid 250 mg Capsule (Metaflam)	DR-XY25587	107165	Feb 2015	Feb 2017
			136165	Sep 2015	Sep 2017
8	Cotrimoxazole 400 mg/80 mg Capsule (Trimocom)	DR-XY34131	104325	Jan 2015	Jan 2017
9	Guaifenesin + Salbutamol (as Sulfate) 100 mg/2 mg Capsule (Venalax XPT)	DR-XY32400	109365	Feb 2015	Feb 2017
			114365	May 2015	May 2017
			120365	Jun 2015	Jun 2017
			130365	Aug 2015	Aug 2017
			140365	Oct 2015	Oct 2017
10	Paracetamol 100 mg/mL Suspension (Oral Drops) (Corgic)	HRP-049	204085	Feb 2015	Feb 2018
			210085	May 2015	May 2018
			219085	Jul 2015	Jul 2018
11	Paracetamol 125 mg/5 mL Suspension (Corgic)	HRP-047	233094	Nov 2014	Nov 2016
			238094	Dec 2014	Dec 2016
12	Paracetamol 250 mg/5 mL Suspension (Corgic Plus)	DR-XY18714	237104	Dec 2014	Dec 2017
			201105	Jan 2015	Jan 2018
			206105	Mar 2015	Mar 2018
			211105	May 2015	May 2018
			220105	Jul 2015	Jul 2018
			221105	Aug 2015	Aug 2018
			227105	Oct 2015	Oct 2018
			228105	Oct 2015	Oct 2018
			231105	Oct 2015	Oct 2018
13	Paracetamol 250 mg/5 mL Suspension (Detramol)	DRP-1604-01	235484	Nov 2014	Nov 2016
			214485	May 2015	May 2017
14	Brompheniramine Maleate + Phenylephrine 4 mg/12.5 mg per 5 mL Syrup (Respitapp)	DR-XY41311	234274	Nov 2014	Nov 2016

15	Salbutamol (as Sulfate) 2 mg/5 mL Syrup (Venalax)	DRP-806	239354	Dec 2014	Dec 2016
			205355	Mar 2015	Mar 2017
			216355	Jun 2015	Jun 2017
			225355	Sep 2015	Sep 2017
			230355	Oct 2015	Oct 2017
16	Guaifenesin + Salbutamol 50 mg/1 mg per 5 mL Syrup (Venalax XPT)	DR- XY36081	236374	Nov 2014	Nov 2016
			218375	Jun 2015	Jun 2017
17	Carbocisteine 50 mg/mL Syrup (Oral Drops) (Aflem)	HRP-059	208025	Mar 2015	Mar 2017
			229025	Oct 2015	Oct 2017
18	Carbocisteine 100 mg/5 mL Suspension (Aflem)	HRP-048	202045	Feb 2015	Feb 2017
			213045	May 2015	May 2017
19	Carbocisteine 250 mg/5 mL Suspension (Aflem Forte)	DR- XY9319	215035	Jun 2015	Jun 2017
20	Mefenamic Acid 50 mg/5 mL Suspension (Metaflam)	DR- XY35963	224175	Sep 2015	Mar 2017
21	Ascorbic Acid 100 mg/5 mL Syrup (Neo- C)	DRHR- 1164	203195	Feb 2015	Feb 2017
22	Brompheniramine Maleate + Phenylephrine Hydrochloride 2 mg/6.25 mg per mL Syrup (Oral Drops) (Respitapp)	DR- XY40182	233265	Feb 2015	Feb 2017
23	Cotrimoxazole 200 mg/40 mg per 5 mL Suspension (Trimocom)	DR- XY6025	207345	Mar 2015	Mar 2017
			223345	Sep 2015	Sep 2017

The cited product lots are being recalled from the market because of non-conformance of the manufacturer to Good Manufacturing Practice (GMP) standard. There is no assurance that they are safe, effective or of good quality. Thus, they present safety risks and possible health consequences.

Distributors, retailers, hospitals, pharmacies or clinics that have any lot of the stated drug products manufactured by Accord Bio Laboratories are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product lots and may contact Accord Bio Laboratories at telephone no. (02) 936-3498 or mobile no. +63 922 8512562 or e-mail us at info@fda.gov.ph for any question or additional information regarding the recall.

All Officers of the Field Regulatory Operations Office (FROO) are ordered to monitor the availability of the affected product lots in the market, appropriately seal discovered stocks of the same, and instruct the concerned establishment to give back the sealed stocks to the Marketing Authorization Holder (MAH) for proper destruction to be witnessed by an appropriate FDA Representative.

Any suspected adverse reaction experienced from the use of the said lots of the products should be reported immediately to FDA by visiting www.fda.gov/adr-report-new and accomplishing all of the required fields.

Dissemination of the information to all concerned is requested.



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Director General