

7/23/15

Re: Question concerning barcode stickers covering original lot number and expiration date on ABILIFY® (aripiprazole) tablet bottles.

Dear Wholesaler,

Otsuka America Pharmaceutical, Inc. (OAPI) relies on third-party organizations to package and distribute its ABILIFY (aripiprazole) tablets product in the United States. In order for the distributors to accept the finished product into their inventory systems, the lot number information had to be changed to a 10-digit lot number from the original 11-digit number. The “oversticker” label was produced and placed over the lot number and expiration date imprint area of the ABILIFY bottle label in accordance with this change.

OAPI confirms that ABILIFY tablets with the oversticker on the bottle label are authentic and the lot number and expiration date on the oversticker are true and accurate.



Enclosed is a list of ABILIFY tablets lot numbers affected by this change.

We regret any inconvenience you may have experienced and will continue to monitor the feedback received to improve our product's performance and overall quality systems.

At OAPI, our mission is to develop and bring to market high-quality products that meet the medical and clinical needs of healthcare professionals and their patients. Each batch of ABILIFY tablets is required to meet specific manufacturing and testing standards prior to release to the market.

As a quality-conscious organization, our products' safe and effective performance, as well as healthcare professional and patient safety and satisfaction, are important to us. Should you have any future concerns, please feel free to contact us at 1-800-438-9927 at any time.

Yours sincerely,



Sanket Shah
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**ABILIFY® (aripiprazole) Tablets Lot Numbers
With “Oversticker” on the Bottle Label**

ABILIFY Dosage Strength	Oversticker Lot Number	Expiration Date
2 mg	AJS01415	11/30/2016
2 mg	AJS01515	11/30/2016
2 mg	AJS01615	11/30/2016
2 mg	AJS02815	11/30/2016
2 mg	AJS03715	11/30/2016
2 mg	AJS03815	11/30/2016
5 mg	AKS00615	10/31/2017
5 mg	AKS00715	10/31/2017
5 mg	AKS00815	11/30/2017
5 mg	AKS00915	11/30/2017
5 mg	AKS02415	11/30/2017
10 mg	ALS01015	11/30/2017
10 mg	ALS01115	11/30/2017
10 mg	ALS02515	11/30/2017
15 mg	AMS01215	11/30/2017
15 mg	AMS03615	11/30/2017
20 mg	ANS01815	11/30/2017
20 mg	ANS02015	11/30/2017
20 mg	ANS03915	11/30/2017
30 mg	APS00115	12/31/2017
30 mg	APS00215	12/31/2017
30 mg	APS00315	12/31/2017
30 mg	APS00515	12/31/2017