



PRODUCT RECALL RESPONSE FORM

URGENT DRUG RECALL - RETAIL LEVEL

Please complete the required information and fax it to **1-817-868-5362**
or email to rxrecalls@inmar.com

To the Attention of Drug Safety/ Recall Services-Zydus Pharmaceuticals USA Inc.

Table:1

Product	NDC Number	Lot Number	Expiry Date	Number of Bottles Purchased	Number of the Bottles Consumed	Number of Bottles in Possession	Number Bottles to be returned
Entecavir Tablets, USP 0.5 mg	68382-920-06	E309376	11/2025				
Entecavir Tablets, USP 1 mg	68382-921-06	E309377	11/2025				

No. of Returns kit required: _____

Please mark as applicable

We currently do not have any inventory of the above-listed Lot/bottles

We are notifying our customers

We have identified and notified my customers that were shipped or may have been shipped this product by _____;

Office of Regulatory Affairs

Zydus Pharmaceuticals (USA) Inc.

(A wholly owned subsidiary of Zydus Lifesciences Limited)

73 Route 31 North • Pennington, NJ 08534 | Phone: 609-730-1900 | Fax: 609-730-1999



Pharmaceuticals

USA

___ Attached is the list of customers who received/ may have received this product. Please notify my customers.

Any adverse event associated with recalled product? ___ Yes ___ No

If yes, please explain:

Please check appropriate box to describe your business

___ Wholesaler/Distributor

___ Retailers

___ Repackager

___ Manufacturer

___ Pharmacy- Retail

___ Hospital/ Medical Facility

___ Hospital Pharmacies

___ Medical Laboratory

___ Other: _____

Name: _____

Title: _____

Tel Number: _____

Firm Name: _____

DEA# _____

Address: _____

Office of Regulatory Affairs

Zydus Pharmaceuticals (USA) Inc.

(A wholly owned subsidiary of Zydus Lifesciences Limited)



Pharmaceuticals

USA

City/ State: _____

Phone number: _____

If you have not purchased, the concerned lot directly from Zydus Pharmaceuticals USA Inc., then please provide details of your wholesaler: _____ (Name, City) DEA# _____

Signature: _____

Date: _____

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