



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	E409308	12/2026				
Entecavir Tablets, USP 1 mg	68382-921-06	E409309	12/2026				

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



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)

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



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: _____

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