State of Florida Department of Business & Professional Regulation Division of Drugs, Devices, and Cosmetics

NOTIFICATION OF REPORTABLE DRUG PRICE INCREASE Form No.: DBPR-DDC-248 Transaction Code: 9021

FORM CHECKLIST - IMPORTANT - Submit all items on the checklist below.

FORM	FORM REPORTING REQUIREMENTS			
Notification of Reportable Drug Price Increase	Effective July 1, 2023, prescription drug manufacturers licensed with the state of Florida must provide notification to the Department of Business & Professional Regulation of each reportable drug price increase on the effective date of such reportable drug price increase as required under Section 499.026, Florida Statutes ("F.S.").			
	Submit the completed form to: Department of Business & Professional Regulation 2601 Blair Stone Road Tallahassee, FL 32399-1047			

DEFINITION OF TERMS PER SECTION 499.026, F.S.

TERMS

Course of therapy: The recommended daily units of a prescription drug pursuant to its prescribing label for 30 days or the recommended daily dose units of a prescription drug pursuant to its prescribing label for a normal course of treatment which is less than 30 days.

<u>Manufacture</u>r: A person holding a prescription drug manufacturer or a nonresident prescription drug manufacturer permit under s. 499.01.

Prescription drug: Has the same meaning as in s. 499.003 and includes biological products but is limited to those prescription drugs and biological products intended for human use.

Wholesale acquisition cost ("WAC"): With respect to a prescription drug or biological product, the manufacturer's list price for the prescription drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing guides or other publications of drug or biological product pricing data.

Reportable drug price increase: Means, for a prescription drug with a WAC of at least \$100 for a course of therapy before the effective date of an increase:

- 1. Any increase of 15 percent or more of the WAC during the preceding 12-month period; or
- 2. Any cumulative increase of 30 percent or more of the WAC during the preceding 3 calendar years. In calculating the 30 percent threshold, the manufacturer must base the calculation on the WAC in effect at the end of the 3-year period as compared to the WAC in effect at the beginning of the same 3-year period.

State of Florida **Department of Business & Professional Regulation Division of Drugs, Devices, and Cosmetics**

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If you have any questions or need assistance in completing this form, please contact the Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, at 850.717.1800.

CURRENT PRESCRIPTION DRUG MANUEACTURER PERMIT INFORMATION

Section I – Current Permit Information

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☐ Prescription Drug Manufacturer – Including Virtual Manufacturer (Physically located in Florida)						
☐ Nonresident Prescription Drug Manufacturer – I	☐ Nonresident Prescription Drug Manufacturer – Including Virtual Manufacturer					
Current Permit Number: Current Expiration Date:						
Section II – Reporting Establishment Information						
BUSINESS NAME AND FEIN AS LIST	TED ON YO	UR MANUFA	CTURER PERMIT			
Name:		FEIN:				
PHYSICAL ADDRES	SS OF EST	ABLISHMEN [*]	Γ			
Street Address:						
City:		State:	Zip Code (+4 optional):			
County (if Florida address):	Country	/:	1			
E-Mail Address:	Phone I Fax Nu	Number: mber:				
NOTIFICATION CONTACT – Name of the person the department should contact if there are questions regarding this notification.						
Last/Surname: First:		Middle:	Suffix:			
Address:						
City:		State:	Zip Code (+4 optional):			
Telephone Number: Fax Number:	E-Mail /	Address:				

Section III - Reportable Drug Price Increase - Use a separate table for each prescription drug

Please provide the following information regarding the reportable drug price increase being reported					
1.	Proprietary name of prescription drug				
2.	Nonproprietary name of prescription drug				
3.	NDC Code:				
4.	Effective date of the reportable drug price increase (mm/dd/yyyy):				
5.	Please indicate which method of reportable drug increase applies to this notification:	☐ WAC increase of 15 percent or more during the preceding 12-month period☐ WAC cumulative increase of 30 percent			
		or more during the preceding 3 calendar years			
6.	What was the WAC prior to the reportable drug price increase?				
7.	What is the dollar amount of the reportable drug price increase?				
8.	What is the percentage amount of the reportable drug price increase from the WAC prior to the reportable drug price increase?				
9.	Has there been a change or improvement in the prescription drug which necessitates the reportable drug price increase?	☐ Yes - If yes, please explain in detail in item #10 below ☐ No			
10.	If there has been a change or improvement in the pre reportable drug price increase, please describe in 500				
11.	Please describe the intended uses of the prescription drug in 500 words or less:				

Mail completed form to:

Department of Business & Professional Regulation 2601 Blair Stone Road Tallahassee, FL 32399-1047