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

ANNUAL NOTIFICATION OF REPORTABLE DRUG PRICE INCREASES
Form No.: DBPR-DDC-249
Transaction Code: 9022

FORM CHECKLIST – IMPORTANT – Submit all items on the checklist below with this form

FORM	FORM REPORTING REQUIREMENTS
Annual Notification of Reportable Drug Price Increases	Effective July 1, 2023, prescription drug manufacturers licensed with the state of Florida must provide an annual list of all prescription drugs affected by a reportable drug price increase as defined by Section 499.026, Florida Statutes ("F.S."). This report must be submitted to the Florida Department of Business & Professional Regulation no later than April 1st of each calendar year.
	Submit the completed notification form to: Department of Business & Professional Regulation 2601 Blair Stone Road Tallahassee, FL 32399-1047

DEFINITION OF TERMS PER SECTION 499.026, F.S.

Definition of Terms Per Section 499.026, F.S.
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.
Manufacturer: 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.

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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.**

Section I – Current Permit Information

CURRENT PRESCRIPTION DRUG MANUFACTURER PERMIT INFORMATION
☐ Prescription Drug Manufacturer – Including Virtual Manufacturer (Physically located in Florida)
☐ Nonresident Prescription Drug Manufacturer – Including Virtual Manufacturer
Current Permit Number: _____ Current Expiration Date: _____

Section II – Reporting Establishment Information

BUSINESS NAME AND FEIN AS LISTED ON YOUR MANUFACTURER PERMIT		
Name:	FEIN:	
PHYSICAL ADDRESS OF ESTABLISHMENT		
Street Address:		
City:	State:	Zip Code (+4 optional):
County (if Florida address):	Country:	
E-Mail Address:	Phone Number: Fax Number:	
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:	Email Address:	

Section III - List all prescription drugs affected by a reportable drug price increase during the previous calendar year. Use separate tables for each prescription drug.

Please provide the following information for each drug reported during the previous calendar year		
1.	Proprietary name of prescription drug	
2.	Nonproprietary name of prescription drug	
3.	NDC Code:	
4.	Provide the dollar amount of the reportable drug price increase.	
5.	Provide the percentage of increase for the reportable drug price increase relative to the previous WAC.	
6.	Have you filed more than one form for reportable drug price increase during the past calendar year? If so, please provide the percentage increase of the reported drug from the earliest form filed to the most recent form filed	☐ Yes ☐ No
7.	Is this prescription drug currently subject to market exclusivity?	☐ Yes ☐ No
8.	Please provide the intended uses of this prescription drug in 500 words or less: _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____	
9.	Please provide the date this drug first became available for purchase.	(mm/dd/yyyy)

10. Indicate each factor contributing to the reportable drug price increase and provide an estimated percentage of the influence of each factor to the overall price increase (the total of all percentages should equal 100%):

	FACTOR	PERCENTAGE
☐	Research and Development	
☐	Manufacturing Costs	
☐	Advertising and Marketing	
☐	Increased Competitive Value	
☐	Increased Rate of Inflation or other economic dynamics	
☐	Changes in Market Dynamics	
☐	Supporting regulatory and safety commitments	
☐	Operating Patient Assistance and Educational Programs	
☐	Rebate Increases	
☐	Medicaid, Medicare, or 340B Drug Pricing Program Offsets	
☐	Profits	
☐	Other factors not listed above. (please list each other factor below). If factors listed above are not utilized, please provide a percentage with each factor listed below, and the estimated percentage related to each respective other factor). _____ _____ _____ _____ _____	_____ _____ _____ _____ _____

11. Provide a description of the justification for each factor referenced in Item 10 in 500 words or less with specificity as to explain the need or justification for the reportable drug price increase:

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	_____ _____ _____
12.	Describe any action which has been filed to extend a patent report after the first extension has been granted in 500 words or less: _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

Mail completed application to:
Department of Business & Professional Regulation
2601 Blair Stone Road, Tallahassee, FL 32399-1047