DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

RIGHT TO TRY REPORTING REQUIREMENT: ANNUAL SUMMARY

Form Approved:
OMB No. 0910-0893

Expiration Date:
Month XX, 20XX

FDA

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information is 0910-0893 and it expires xx/xx/xxxx. The time burden for this collection of information is estimated to average 2.5 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the information to FDA.

Calendar Year Reporting Period	Submitter Name	Submitter Email Address

Name of Manufacturer or Sponsor

Eligible Investigational Drug[1]	IND Number[1]	Number of Doses Supplied[2]	Number of Patients Treated[3]	Disease(s) or Condition(s)[4]	Serious Adverse Event(s)[5]	
					SAE(s)	Outcome(s)
EXAMPLE: XDX501	**EXAMPLE:** 9999999	**EXAMPLE:** 5	**EXAMPLE:** 1	**EXAMPLE:** Breast cancer	**EXAMPLE:** 1. Hip fracture 2. Joint pain	**EXAMPLE:** 1. Improved 2. Improved

OPTIONAL: Additional contextual information (e.g., time between dose received and onset of serious adverse event)

(Footnotes)

[1] The name and IND number of the eligible investigational drug supplied by the manufacturer or sponsor for use under section 561B of the Federal Food, Drug, and Cosmetic Act.

[2] The total number of doses supplied by the manufacturer or sponsor to eligible patients for use under section 561B of the Federal Food, Drug, and Cosmetic Act. Each dose of an eligible investigational drug supplied for an eligible patient shall be counted as a dose supplied.

[3] The total number of eligible patients for whom the manufacturer or sponsor provided the eligible investigational drug for use under section 561B of the Federal Food, Drug, and Cosmetic Act. An eligible patient treated more than one time or with multiple doses of an eligible investigational drug shall be counted as a single patient.

[4] The disease or conditions for which the eligible investigational drug was made available for use under section 561B of the Federal Food, Drug, and Cosmetic Act.

[5] Any known serious adverse events, including resulting outcomes, experienced by patients treated with the eligible investigational drug under section 561B of the Federal Food, Drug, and Cosmetic Act.

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