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Updates from FDA/CDER: Pediatric Information Incorporating Into Human Prescription Drug and Biological Product Labeling

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Prescribing Information (PI)

- Written for healthcare practitioners and must:[1]
  - Contain a summary of essential scientific information needed for safe and effective use of **human prescription drug and biological products**
  - Be informative and accurate and neither promotional in tone nor false or misleading
  - Be updated when new information becomes available that causes labeling to become inaccurate, false, or misleading
- There are only two PI formats:
  - "Physician Labeling Rule" (PLR) labeling[2] (based on 2006 rule)
  - "Old" (non-PLR) format labeling[3] (based on 1979 rule)

[1] 21 CFR 201.56(a)(1) and (2); [2] 71 FR 3922 (January 24, 2006); [3] 44 FR 37434 (June 26, 1979)

Pediatric Labeling Guidance (March 2019)

Pediatric Information Incorporated Into Human Prescription Drug and Biological Product Labeling
Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

March 2019
Labeling

Four Scenarios for Including Pediatric Use Information in Labeling

- Evidence supports safety and effectiveness of drug for a pediatric indication (Scenario #1)
- Evidence does **not** support safety and effectiveness of a drug for a pediatric indication:
  - Scenario #2: Results of pediatric studies were negative or inconclusive
  - Scenario #3: No evidence available because studies have not been conducted or are ongoing
  - Scenario #4: Drug is contraindicated in pediatric patients

Scenario #1: Drug Has a Pediatric Indication - *Pediatric Use* Subsection

8 USE IN SPECIFIC POPULATIONS

…

8.4 Pediatric Use

Pediatric Use Statement

"The safety and effectiveness of DRUG X (for Indication Y) have been established in pediatric patients aged 6 years and older. Use of DRUG X for this indication is supported by evidence from adequate and well-controlled studies in adults with additional pharmacokinetic and safety data in pediatric patients aged 6 years and older *[see Adverse Reactions (6.1), Clinical Pharmacology (12.3), and Clinical Studies (14.1)].*"

Basis of Approval Statement

Pediatric Use Information Should be Consistent Throughout the Labeling[1]

1 INDICATIONS AND USAGE

DRUG X is indicated for the treatment of Indication Y in adults and pediatric patients aged 6 years and older.

8 USE IN SPECIFIC POPULATIONS

8.4 Pediatric Use

The safety and effectiveness of DRUG X (for Indication Y) have been established in pediatric patients aged 6 years and older.

1 According to the Draft Guidance for Industry: *Indications and Usage Section of Labeling Guidance (July 2018)*, *"age groups should be included in indications"* (when finalized this guidance will represent FDA's current thinking)

Scenario #2: No Pediatric Indication Because Pediatric Study Results are Negative or Inconclusive: *Pediatric Use* Subsection

8 USE IN SPECIFIC POPULATIONS

Pediatric Use Statement

…

8.4 Pediatric Use

The safety and effectiveness of DRUG X have not been established in pediatric patients (for Indication Y). Effectiveness was not demonstrated in two adequate and well-controlled studies conducted in 120 DRUG X-treated pediatric patients, aged 6 to younger than 17 years for Indication Y.

Relevant pediatric information related to unapproved pediatric use

Scenario #3: No Pediatric Indication Because Studies Have Not Been Conducted or are Ongoing: *Pediatric Use* Subsection

8 USE IN SPECIFIC POPULATIONS

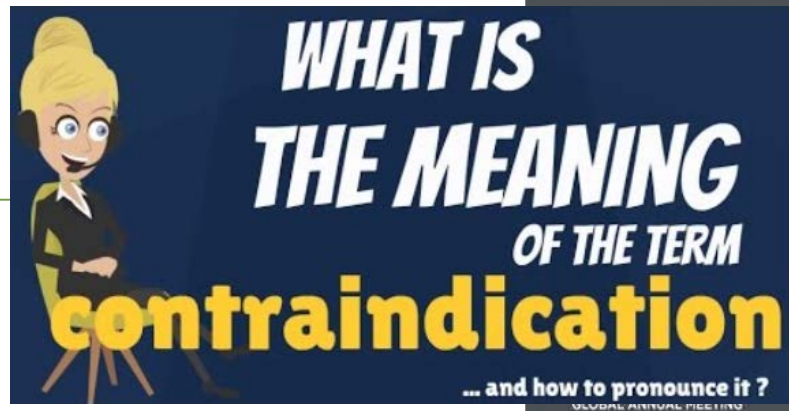
…

8.4 Pediatric Use

The safety and effectiveness of DRUG X have not been established in pediatric patients.

Pediatric Use Statement

Scenario #4: Drug is Contraindicated in Pediatric Patients



If a drug is contraindicated in pediatric patients, should state the contraindication and reason for contraindication in the beginning of the *Pediatric Use* subsection. For example:

8 USE IN SPECIFIC POPULATIONS

...

8.4 Pediatric Use

DRUG X is contraindicated in pediatric patients younger than 1 year of age because of an increased risk of systemic toxicity, including marked increases in blood pressure *[see Contraindications (4) and Warnings and Precautions (5.X)].*

Want to Learn More About Labeling?

2019 CDER Prescription Drug Labeling Conference[1]

Topics:

Updates: Prescribing Information, carton/container labeling, and FDA-approved patient labeling

Logistics:

- December 4th and 5th, 2019
- "The HOTEL" at the University of Maryland in College Park, Maryland
- Check website for online or in person registration: https://www.fda.gov/drugs/development-approval-process-drugs/cder-small-business-industry-assistance-sbia

[1] CDER Small Business & Industry Assistance (SBIA): Regulatory Education for Industry (REdI)

Thank You!

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- For general questions about the Prescribing Information: See the Labeling Development Team webpage: https://www.fda.gov/about-fda/center-drug-evaluation-and-research/labeling-development-team
- For specific questions about labeling under an NDA, BLA, or ANDA: Please contact the regulatory project manager assigned to the application

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