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What is the drug name used here



The document doesn't mention a specific drug name. It appears to be a general guidance document from the FDA on the "Periodic Benefit-Risk Evaluation Report (PBRER)" for industry, and it doesn't reference a particular medicinal product.



Can you summarize the whole document



The document is a guidance for industry on the "Periodic Benefit-Risk Evaluation Report (PBRER)" from the FDA. Here's a summary of the document:

Introduction

The PBRER is a report that evaluates the benefits and risks of a medicinal product. It's intended to be a common standard for periodic benefit-risk evaluation reporting among ICH regions.

Objectives

The main objective of a PBRER is to present a comprehensive, concise, and critical analysis of new or emerging information on the risks and benefits of a medicinal product.

Scope

The PBRER should include information on all approved indications, dosage forms, and regimens for the active substance. It should cover both safety and efficacy/effectiveness information.

General Principles

- A single PBRER should be prepared for an active substance.
- The report should have a single data lock point (DLP).
- The level of detail should be proportional to the product's known or emerging benefits and risks.

Content

The PBRER should include:

1. Introduction
2. Worldwide marketing approval status
3. Actions taken in the reporting interval for safety reasons
4. Changes to reference safety information

5. Estimated exposure and use patterns
6. Data in summary tabulations (serious adverse events from clinical trials and post-marketing data)
7. Summaries of significant findings from clinical trials
8. Findings from non-interventional studies
9. Information from other clinical trials and sources
10. Nonclinical data
11. Literature
12. Other periodic reports
13. Lack of efficacy in controlled clinical trials
14. Late-breaking information
15. Overview of signals: new, ongoing, or closed
16. Signal and risk evaluation
17. Benefit evaluation
18. Integrated benefit-risk analysis for approved indications
19. Conclusions and actions
20. Appendices

Key Concepts

- Signals: new or emerging information that suggests a potential causal association between a medicinal product and an adverse event



Can you summarize the whole document in 100 words



The FDA guidance document outlines the Periodic Benefit-Risk Evaluation Report (PBRER) for industry. The PBRER evaluates the benefits and risks of a medicinal product, covering safety and

efficacy/effectiveness information. The report should be comprehensive, concise, and critical, and include various sections such as introduction, worldwide marketing approval status, and signal and risk evaluation. The level of detail should be proportional to the product's known or emerging benefits and risks. The PBRER aims to provide a common standard for periodic benefit-risk evaluation reporting among ICH regions, facilitating regulatory submissions and decision-making. It's a modular and flexible document.

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