

Regulatory Insight Guidance and Policy

Explore agency guidance and policy documents that implement and clarify Federal regulations

ProQuest Insight products are select collections of U.S. government documents with workflow functionality to facilitate research, teaching, and learning involving historic and current legislative, judicial, and executive branch materials. Primary source content in each collection is compiled by our professional research staff and made accessible through a user-friendly, dynamic workspace allowing for easy, in-depth discovery. Links between collections enhance the value of the individual collections, facilitating understanding of government processes and multiple viewpoints. The Insight product features empower users to focus on what really matters – achieving superior research results.

Opioid Analgesic Drugs: Considerations for Benefit-Risk Assessment Framework Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact Sharon Hertz at 301-796-1225.

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

June 2019
Clinical/Medical

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06/03/19

ProQuest is pleased to announce the latest Regulatory Insight Collection, Regulatory Insight Guidance and Policy – available as a stand-alone or a fully integrated, cross-searchable module on ProQuest Regulatory Insight.

A Regulation Has Been Promulgated... What Happens Next?

Regulatory Insight Guidance and Policy offers a unique collection of Federal agency guidance and policy documents harvested from government websites. The documents in this collection explain, summarize, and clarify regulations, and may suggest steps both organizations and consumers can take to comply with requirements.

Until now...Guidance and policy documents have not been collected systematically in a single place. They may be hard to find and not be labeled as guidance documents on an agency website. They can go into an agency archive where they are hard to retrieve, or disappear entirely. Our archive will ensure continued access to documents as agencies replace them over time with new guidance documents.

ProQuest Regulatory Insight

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Search filters: AND, Limit by: Date, Administration, All available dates

DRAFT



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Regulatory Insight Guidance and Policy offers features that allow users to:

- Simultaneously search guidance and policy, and Federal Register collections for a single agency, or across multiple agencies.
- View guidance and policy documents for an agency.
- Retrieve similar documents using high-level subject indexing.

Superior functionality to reduce research churn, documents are:

- Searchable by type of guidance document, including memorandum, manuals, bulletins, letters, and much more.
- Links, where possible, from guidance documents to related documents, such as Federal Register articles or CFR Parts.
- Post-search filters by agency, subject, or Administration.

Regulatory Insight Guidance and Policy provides users with the unique opportunity to:

- Locate guidance documents associated with current events.
- Compare guidance documents issued during different Administrations.
- Cross-search guidance documents with Federal Register “articles.”
- Locate guidance documents cited in Federal Register notices asking for comments.

The collection will be fully loaded by the end of 2020 and updated on an ongoing basis. This initial module—including data going back to the 1970s—will encompass data published through 2021. Post-2021 data will be available as a separately priced offering.

Regulatory Insight Products:

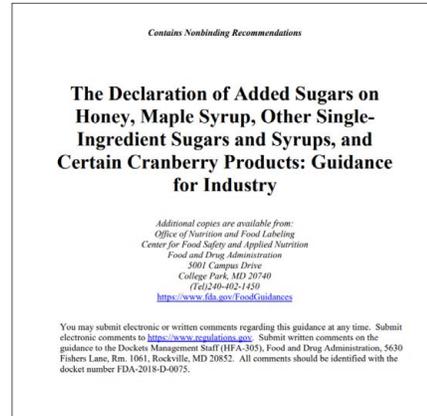
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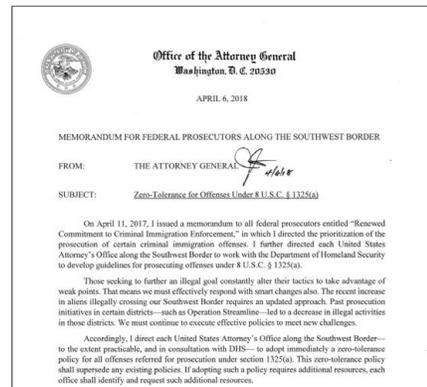
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Examples of guidance documents

- Guidance for Industry: Declaration of Added Sugars on Honey, Maple Syrup, Other Single-Ingredient Sugars and Syrups, and Certain Cranberry Products



- Memorandum for Federal Prosecutors along the Southwest Border



- The Use of Race in Postsecondary Student Admissions

