TRUVEN HEALTH ANALYTICS™

# Process for Requesting Inclusion of Off-Label Information in Micromedex Databases

Truven Health Analytics™ is recognized worldwide as a provider of unbiased information in the areas of drugs, disease, and toxicology. Our Micromedex® Solutions content facilitates the practice of evidence-based medicine whereby the clinician can identify best practices and choose the most appropriate treatment plan for a specific patient.

The proprietary, unbiased information contained in Micromedex Solutions is based on an ongoing editorial review of primary literature published in thousands of peer-reviewed journals, as well as FDA-approved product labeling. Inclusion of information is determined through identification of relevant literature and through the use of validated and documented literature evaluation techniques that assess methodological rigor, appropriateness of statistical analyses, and clinical relevance. Our surveillance of the literature is extensive and continuous.

## External Requests for Inclusion of Information

In addition to rigorous internal processes, Truven Health occasionally receives external requests for inclusion of information in our Micromedex databases. We adhere to a policy under which external requests may be submitted for consideration. Please forward one complete bibliography of information to be considered via email (**offlabelsubmissions@truvenhealth.com**) or in writing.

This request must include the following:

- Name of requestor
- Date of submission
- Affiliation of requestor (e.g., name of pharmaceutical company, organization, institution, etc.)
- Disclosure of relevant financial relationships with a bearing on the drug(s) or product(s) in question
- Contact information including address, phone number, and email address
- Identification and brief explanation of request (should clearly indicate if request involves a patient safety issue)
- If applicable, a statement describing the proposed indication including:
  - Specific disease state
  - Specific patient population
  - Whether the treatment involves mono- or combination therapy
- If the treatment involves combination therapy, address specific components of the therapy

We are unable to provide any feedback or response regarding any literature/evidence submitted. All requests will be reviewed in accordance with established policies on content development, including the Policy on Off-Label Indications. Furthermore, if submitted information warrants inclusion in Micromedex databases, we cannot provide the requestor with a prepublication copy of text. Finally, the inclusion or exclusion of information in our databases, as well as assignment of an efficacy rating or other relevant ratings, are at the sole discretion of our editorial staff.

Truven Health reserves the right to modify its policy on requesting inclusion of information in its databases as deemed appropriate.

**Submissions should be mailed to:**
Truven Health Analytics
Attn: Editorial Assistant
6200 S. Syracuse Way, Suite 300
Greenwood Village, CO 80111
or electronically to: **offlabelsubmissions@truvenhealth.com**

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