Important Aspects of the NDIN Process

The U.S. Food and Drug and Administration's (FDA) new dietary ingredient notification (NDIN) process for dietary supplements allows FDA to obtain critical identity and safety information about dietary supplements and their ingredients before they are available on store shelves.

Manufacturers and distributors who wish to market a dietary supplement containing a new dietary ingredient (NDI) are required to submit an NDIN to notify FDA. **This fact sheet highlights important aspects that can simplify this process for manufacturers and distributors and help them to successfully submit a complete NDIN.**

What common issues has FDA observed in the NDIN submission process?

There are various common issues that can cause delays in FDA's processing of an NDIN or lead to a negative response. These instances include when:

1 The NDIN does not concern a dietary ingredient

The dietary ingredient categories an NDI belongs to should be specified with an explanation of the basis for the conclusion. A dietary ingredient in a dietary supplement may include any from the following categories:

- A vitamin, such as vitamin C, D, or E;
- A mineral, such as calcium, potassium, or iron;
- An herb or other botanical, such as elderberry, ginger, or green tea;
- An amino acid, such as leucine or alanine;
- A dietary substance for use by people to supplement the diet by increasing the total dietary intake, such as certain live microbials, commonly known as probiotics; or
- A concentrate, metabolite, constituent, extract, or combination of any dietary ingredient from the categories above.

2 The NDIN does not cover the broadest possible use of the NDI

In some cases, manufacturers do not submit an NDIN because they believe the ingredient was covered by another NDIN that was not objected to by FDA. However, an NDIN for one manufacturer's product does *not* eliminate the need for another manufacturer to submit an NDIN for their product.

If you are not sure about whether to submit an NDIN for your product, email FDA at NDITeam@fda.hhs.gov.

3 The NDIN does not include sufficient identity information

Notifications are more likely to be successful when FDA has a complete understanding of the identity of the NDI and how the scientific evidence supports it.

An NDIN should include the following identity information:

- A description of the manufacturing process used to make the NDI, including process controls;
- A description of the physical properties and chemical or molecular composition and structure of the NDI; and
- A specification sheet that describes the critical identity and safety attributes of the NDI (this includes the purity and strength of the NDI and the identities and levels of any impurities and contaminants).

4 The NDIN includes irrelevant information to support the notifier's conclusions

While the safety narrative and scientific evidence are crucial to a comprehensive NDIN, a notification should not contain irrelevant or extraneous information.

The NDIN should focus on providing information about:

- The identity of the NDI;
- A description of the dietary supplement containing the NDI; and
- The data and information that provide a basis for concluding that the NDI is reasonably expected to be safe when used as recommended.

It is not useful to include publications or information that promote the product or other products, unless that information can be specifically linked to the identity or safety of the NDI or dietary supplement.

5 The notifier fails to submit proper references and/or copies of referenced articles or other underlying materials to support the safety of their NDI

Copies of any articles and other supporting information referenced in the NDIN must be provided to satisfy the requirement that all references to published information be accompanied by the full text of the cited article.

Recommendations to meet this guidance include the following:

- Submit a PDF or scanned copy of each reference cited for electronic submissions.
- Submit a photocopy of the full text of each reference cited if submitting your NDIN on paper. An abstract or bibliographic citation of a publication is not sufficient.
- Provide a complete and accurate English translation of any materials or data in a foreign language that were cited or used as part of the NDIN.
- Do not provide any general links to a reference repository that requires additional searching.

For the complete summary of FDA's recommendations regarding the NDIN process, please review our guidance on NDIN submissions and other NDIN-related information at

www.fda.gov/dietarysupplements