The Food and Drug Administration's Database Review System

Jean A.T. Pennington, Ph.D., R.D., U.S. FDA

Background

In 1973, the Food and Drug Administration (FDA) made available a manual, Compliance Procedures for Nutrition Labeling, which explained how the agency would conduct evaluations of the nutrient content of retail products to determine if the information on the label was in compliance with FDA nutrition labeling regulations. The 1973 manual was updated, revised, and replaced in 1993 by the FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases. The 1993 manual was supplementary to the nutrition labeling regulations which were revised and published in the Federal Register on January 6, 1993. The manual describes the development of acceptable nutrient databases and discusses the statistical methodology to develop nutrition labeling values. It was written specifically to assist the food industry in developing nutrition labels for food products that comply with the nutrition labeling regulations.

In the nutrition labeling regulations, which were published on January 6, 1993, FDA provided information regarding the use of databases for nutrition labeling. FDA encouraged manufacturers who wished to use a database for nutrition labeling to follow the statistical procedures outlined in the 1993 FDA Nutrition Labeling Manual and to have the database reviewed and approved by FDA. Specifically, the agency stated:

> If a manufacturer wishes to use a data base for nutrition labeling, it is advantageous to follow the statistical procedures outlined in the manual and have the data base accepted by FDA. If the agency finds that the nutrition label of a product which is based on a data base that has been accepted by FDA is not in compliance with § 101.9, FDA will not take immediate action against the product, provided that the company has followed good manufacturing practices in producing the foods. Instead, the agency would work with the manufacturer to resolve the compliance issue. Action would be taken only if noncompliance was the result of failure to follow good manufacturing practices.

When FDA refers to a database in the nutrition labeling regulations, it is referring to the collection of data and other relevant information about an individual food. (The term "database" also refers to reference databases containing many foods, such as USDA Agriculture Handbook No. 8; however, FDA is not using the term in this way.) The relevant information includes previous studies about variables that affect the nutrient content of the food, sampling design, analytical methods, laboratory quality control, and statistical treatment of the nutrient composition data. Databases that are submitted to FDA may contain proprietary information that cannot be released by the agency to others who may request it.

In the January 6, 1993 publication, FDA made it clear that the data used for nutrition labeling are the choice and responsibility of the manufacturer. FDA stated

It must be noted that submission of a data base to FDA for review and acceptance is voluntary. The agency has not prescribed how an individual company is to determine nutrient content for labeling purposes. The choice of a data source is the prerogative of the manufacturer. The manufacturer needs to be judicious in this selection, however, to ensure that the product labeling is in compliance with the regulations.

The nutrition labeling regulations (21 CFR 101.9(g)(8)) state that compliance with nutrition labeling regulations "may be provided by use of an FDA approved data base that has been computed following FDA guideline procedures and where food samples have been handled in accordance with current good manufacturing practice to prevent nutrition loss. FDA approval of a data base shall not be considered granted until the CFSAN has agreed to all aspects of the data base in writing." The regulations further state that "approvals will be in effect for a limited time, e.g., 10 years, and will be eligible for renewal in the absence of significant changes in agricultural or industry practices."

Current Situation

In response to FDA's statements about databases, several food companies and trade associations have submitted databases and ingredient database systems to FDA for review and evaluation. (Ingredient database systems determine the nutrient values for foods from the nutrient content of their ingredients.) Approximately 48 submissions are currently under review at FDA. Over the past year, the agency has been developing a review system to provide consistent and thorough evaluations of the submissions. FDA developed and made available the Guide to FDA's Database Review System to provide assistance to industry, trade associations, and other groups who are developing and submitting food composition databases for use in nutrition labeling to FDA for review and evaluation. The Guide describes the FDA database review process and provides the criteria that FDA currently uses for individual food databases. The Guide also addresses criteria for ingredient databases; however, this section is still under development.

The review of individual databases consists of four parts:

1. Data reasonableness and variables
2. Analytical methods (shipping, handling, storage, quality control, sample preparation, laboratory controls)
3. Sampling design (sampling objectives, target population and sampled population, sampling frame, sample size, sample collection and handling, types of test samples)
4. Statistical treatment of data (statistical analysis and calculations of label values)

Reviewers with specific expertise in these four areas evaluate the databases using the criteria specified in the Guide.

The review of ingredient database systems consists of a series of questions that relate to:

- the suitability of the ingredient database system for the particular food products
- background information regarding the development of the system
- variables that affect the nutrient content of the food and/or the major ingredients
- the ingredient database (number of ingredients, source of data, completeness of database, how information is collected and reviewed)
- procedures to ensure accuracy and currency of the database
- corrections for moisture and nutrient loss
- validation process; sample collection and analytical methods for validation; comparison of calculated and analytical values
- the software system description and validation.

The reviewers respond to the questions and provide overall summary evaluations for the systems.

Several problems have become apparent during the review process. First, FDA resources for database review are not adequate to handle the volume of submissions received by the agency. FDA is trying to decide how to accommodate the interest in agency review and approval for databases, and the assurances provided by that approval, while maintaining a system that is responsive to review requests, i.e., a system that provides reasonable, timely responses to requests for agency review but does not overwhelm its resources.

Secondly, the rigorous standards set in the 1993 FDA Nutrition Labeling Manual are not being reached by the submissions. These standards are generic (for all foods) and represent the ideal situation. FDA acknowledges the effort of industry to develop nutrient databases for nutrition labeling, but notes that there is a gap between the databases/database systems that FDA would like to receive and the databases/database systems which the food industry is currently submitting. The primary problems found during the review process include lack of documentation, lack of information about variables that affect nutrient content, and inappropriate sampling designs. Although several database evaluation letters have been sent to industry from the agency, FDA is trying to find a workable solution that is fair to industry, but still provides consumers with appropriate, useful labeling information.

The FDA Nutrition Labeling Manual evolved during the period of voluntary nutrition labeling when only those industries truly interested in nutrition labeling were developing databases for their products. Nutrition labeling is now mandatory for most manufacturers, and many of them are providing nutrition labeling for their products for the first time. Industry appears to be concerned about the "stringent" database review criteria developed by FDA. The agency receives many visits, calls, and questions from industry regarding database development and use and the status of their submissions. We do our best to answer their questions, to meet with them, and provide assistance without showing partiality or favoritism.

Actions and Directions

Based on the database review concerns noted above, i.e., inadequate resources and standards that industry has difficulty meeting, FDA believes that some modifications in its approach to databases may be necessary. The agency is considering the possibility that it can adequately evaluate a database using less information than it would receive under the guidance in the FDA Nutrition Labeling Manual. It is also considering the possibility that the system may be more flexible and responsive if manufacturers were authorized to begin labeling their products based on an abbreviated, preliminary review by FDA. Such a system could offer a manufacturer some assurance that FDA would not take action against its products,

although the manufacturer would have to agree to move quickly to modify its labeling if the agency found the database to be unrepresentative or inadequate.

FDA has taken two primary actions with regard to databases. One was to grant interim use of submitted databases/ingredient database systems until May 8, 1995. All those submitted to FDA before May 8, 1994 (except those concerning raw fruit, vegetables, and fish) were granted this interim use period. Databases for raw fruit, vegetables, and fish are considered under another regulation, the Voluntary Nutrition Labeling Program. FDA is developing the database for foods in the voluntary program to promote consistent use of the same data in retail stores across the country.

The second action is that FDA solicited comments on all aspects of the FDA database review process. This request for comments is found in the proposal concerning the Voluntary Nutrition Labeling Program which was published in the Federal Register in May 1994. This proposal specifically asks for comments on FDA's database review process and makes available the Guide to FDA's Database Review System. The agency is requesting comments about the evaluation criteria as related to (1) the nature and rigor of the evaluation process, including the need for information on the source of the data, number of samples, sampling design, analytical methods, statistical treatment of data, and proposed quantitative label declarations; and (2) the appropriate basis for an "interim" approval and guidelines to determine key minimal criteria for such "interim" status, as well as guidelines to establish follow-up procedures and time lines to ensure that database developers will continue to collect data and improve their databases intended for nutrition labeling purposes.

FDA will consider and respond to all comments concerning database reviews that are received in response to the proposal, and will revise the database review process accordingly. The end result will hopefully be a database review system that meets the needs and fits within the resource constraints of industry, consumers, and FDA.