

identity of different types of dietary ingredients.

Comments generally supported requiring tests of some kind to positively identify dietary ingredients and to verify dietary ingredient identity. The comments put forth different reasons, which ranged from ensuring public safety to preventing economic adulteration. Some comments suggested that suppliers should be responsible for identifying the dietary ingredients they supply to manufacturers and that manufacturers should be responsible for only verifying the identity of the finished product. Other comments stated that the manufacturer should be responsible for identification and should not rely on a supplier's certification.

Some comments raised issues relating to the actual identity tests that should be recommended or required and discussed analytical method selection and method options, use of and availability of official validated analytical methods, and certification of testing facilities that conduct identity tests on natural products. Some comments suggested that identity test method options should include organoleptic and microscopic methods and chemical analytical methods. The comments noted that selecting the appropriate method is dependent on the type and form of the ingredient. Other comments said that manufacturers should be responsible for selecting the appropriate method to confirm ingredient identity. Most comments recommended that we provide guidance to industry in defining what comprises adequate testing for different types of ingredients, but did not support regulations prescribing the test method or methods for specific ingredients.

Comments generally supported the use of a standard compendial method, such as those published by the USP or AOAC International. Where no published method exists, the comments suggested that manufacturers should be responsible for developing adequate and effective identification testing procedures, requirements, or practices to ensure the identity of the dietary ingredients they use. One comment from a vitamin manufacturer noted that most of its products have recognized and established identity tests as part of their compendial status. Other comments from botanical dietary supplement manufacturers noted that their current methods for identifying plant material are adequate, but that they will, over time, be enhanced by the availability of more widely recognized methods and techniques as a result of current work in this field. The

comments noted that test methods that are presently available and used for identifying botanicals are not officially validated. If an officially validated method is not available for a dietary ingredient, several comments suggested working towards AOAC International validation and, in the interim, instituting peer review of less formal test methods. Other comments noted that the dietary supplement industry has begun an effort to develop validated test methods for several botanical ingredients. One comment suggested that it is important to develop methods that are subject to peer review and to institute a certification program for testing facilities because the analysis of natural products requires specialized training in natural product chemistry. The comment did not indicate who (*e.g.*, FDA or another organization) should develop a certification program.

Some comments only addressed identity testing of unprocessed botanicals. These comments said that for unprocessed botanicals in whole or in part (*e.g.*, flowers, roots, leaves, etc.), organoleptic techniques are sufficient provided that accurate records are maintained and that the manufacturing process provides a paper trail of positive identification. One comment suggested that a "voucher specimen" (a sample of the plant material) from the supplier along with a certificate of botanical identity would be an adequate record. The certificate of botanical identity would follow the material through the manufacturing process, thus creating a paper trail. The voucher specimen would be held for a specific period of time or, if necessary, serve as a permanent record.

Dietary ingredient identification is an important part of CGMPs. We agree with the comments that identity testing requirements are needed but that no single approach or test method may be appropriate for every dietary ingredient. For example, microscopic or organoleptic tests might be appropriate for herbs or plant parts (because you can see, taste, or smell them), but not appropriate for amino acids (which cannot be identified by the naked eye or identified by using your senses). A microscopic test might be appropriate for herbs that still have their leaves or other distinguishing marks or characteristics, but not for ground-up herbs. Thus, we agree with the comments stating that the key principle in dietary ingredient identification testing is to establish an appropriate procedure that will identify, with certainty, the dietary ingredients used in making a dietary supplement. We agree that a guidance document on ingredient

identity testing may be useful, and we will consider future development of ingredient identity testing guidance documents.

Manufacturers should be responsible for identifying the ingredients that they use in their products and, in addition, for verifying that the dietary ingredients or dietary supplements they make contain the identity, purity, quality, strength, and composition that the manufacturer intends the product to have. As discussed previously in this document, we have found serious adverse events to be related to dietary ingredient misidentification. The manufacturer must conduct identity tests to ensure that they used the correct ingredient to prevent potential serious adverse events. We discuss identity testing for dietary ingredients and dietary supplements later in this document.

We agree with the comments that certification of testing facilities could be an important step in ensuring analytical quality. However, certification of testing facilities is outside the scope of this rule.

*Question 3.* FDA requested comments on standards that should be met in certifying that a dietary ingredient or dietary supplement is not contaminated with filth; that it is free of harmful contaminants, pesticide residues, or other impurities; that it is microbiologically safe; and that it meets specified quality and identity standards.

The ANPRM noted that, under § 110.80, a food manufacturer may accept a supplier's certification that its products do not contain microorganisms, filth, or other foreign material that would adulterate the product instead of testing or evaluating the supplier's products itself. As a result, we asked for comments on whether a certification will provide assurance that dietary ingredients are not contaminated or whether specific testing requirements are necessary.

Comments generally supported relying on a supplier's certification that a dietary ingredient is what it purports to be and is not contaminated. The comments stated that reliance on the supplier's certification should be an alternative to testing raw materials to detect microorganisms, filth, or foreign material so long as the reliability of the supplier's certification is confirmed. Most comments stated that manufacturers are responsible for determining, on a case-by-case basis, whether a supplier's certification provides adequate assurance that a dietary ingredient is what it purports to be and is not adulterated. Some comments based their support for