

the risk that such contaminants will enter the compressed air or other gases.

Proposed § 111.25(b)(1) would require that you calibrate your instruments and controls that you use in manufacturing or testing components, dietary ingredients, or dietary supplements. Proposed § 111.25(b)(2) would require that you calibrate before you first use the instruments and controls and either as specified in writing by the manufacturer of the instrument and control or at routine intervals or as otherwise necessary to ensure their accuracy and precision. Calibrating instruments and controls will ensure that they are accurate and precise and that the instrument or control readings are "true values." We invite comment on whether we should require, in a final rule, that you establish and follow a written procedure for calibrating instruments and controls, and whether there are other procedures, that we should consider including in a final rule. If comments assert that written procedures are necessary, comments should include an explanation of why the requirement is necessary to prevent adulteration including how such a requirement would ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. Conversely, if comments assert that written procedures are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength and composition of the dietary ingredient or dietary supplement. Further, we seek comment on whether any of the proposed requirements in this section are not necessary to prevent adulteration and to ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments assert that certain provisions are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments agree that the proposed requirements are necessary for reasons other than those we have provided, the comments should so state and provide an explanation.

Proposed § 111.25(c) would require that you must establish a written procedure for calibrating instruments and controls you use in manufacturing or testing a component, dietary ingredient, or dietary supplement and

document that the written procedure was followed each time a calibration was performed or that you must document, at the time of performance, that the instrument and control calibration established in accordance with this section was performed. The proposed calibration requirement gives you discretion in deciding whether to establish and follow a written calibration procedure. If you establish a written procedure for calibrating instruments and controls, you must document, at the time of calibration performance, that the written procedure was performed. If you do not establish a written calibration procedure then you must document, at the time of performance, that the calibration established accordance with this section was performed. You must identify the following for calibrating instruments and controls in any written procedure or at the time of performance:

- The instrument or control calibrated;
- The date of calibration;
- The reference standard used including the certification of accuracy of the known reference standard and a history of recertification of accuracy. A certification of accuracy usually accompanies a standard reference material and often is valid for a specific period of time, but the supplier of the reference standard may recertify the standard's accuracy. The recertification typically involves testing by the supplier to verify that the material maintains accuracy as a testing reference. This information also may help you trace the source of a problem, if one arises, in your dietary ingredients or dietary supplements. For example, if consumers report an adverse event with a batch of dietary supplements, records containing a certification of accuracy of the reference standards used and a history of their recertification would help you determine if the problem resulted from using an inaccurate reference standard to calibrate your instruments;
- The calibration method used including appropriate limits for accuracy and precision of instruments and controls when calibrating;
- The calibration reading or readings found;
- The recalibration method used if accuracy or precision or both accuracy and precision limits for instruments and controls were not met; and
- The initials of the person who performed the calibration.

These records will enable you to determine whether the calibration schedule can maintain the accuracy of your instruments and controls, and will

also provide information on when and how the instruments and controls were calibrated in case a problem arises with a batch of dietary ingredients or dietary supplements. If you examine these records over time, you also will be able to see how precise your instruments and controls are and to make any necessary adjustments or repairs. For example, if your records show that a scale gives a particular reading for a standard reference weight in January, but then shows a different reading in June for the same standard reference weight, you may need to adjust, repair, or even replace your scale.

In fact, proposed § 111.25(d) would require that you repair or replace instruments and controls that cannot be adjusted to agree with the reference standard. You should not trust any instrument or control that cannot be adjusted to agree with a reference standard because an inaccurate measurement or reading may result in an adulterated dietary ingredient or dietary supplement. Again, to use a scale as an example, if you have a scale that you cannot adjust to read the correct weight, using that scale to weigh a dietary ingredient to be added to a particular mix would cause you to add either too much or too little of the dietary ingredient into your mix, thus throwing your mix out of specification. So, proposed § 111.25(d) would require that you repair or replace that scale.

Proposed § 111.25(e) applies to maintenance and sanitation. The word "maintenance," in this provision, means the act of keeping your equipment and utensils in working order as recommended by their manufacturer. Proposed § 111.25(e)(1) would require that you maintain, clean, and sanitize, as necessary, all equipment, utensils, and any other contact surfaces that are used to manufacture, package, or hold components, dietary ingredients, or dietary supplements and to take apart your equipment and utensils as necessary for thorough maintenance, cleaning, and sanitizing. Obviously, if you fail to keep your equipment, utensils, and contact surfaces clean, you risk contaminating them with microorganisms and other contaminants and risk transferring those microorganisms or other contaminants to anything that touches the equipment, utensils, and contact surfaces.

Proposed § 111.25(e)(2) would require that you ensure that all contact surfaces used for manufacturing or holding low-moisture components, dietary ingredients, or dietary supplements are in a dry and sanitary condition at the time of their use. If the surfaces are wet-cleaned, you must sanitize them, when