U.S. PHARMACOPEIA
The Standard of Quality℠

Food Ingredients Stakeholder Forum
Meeting #1 for the 2010-2015 Cycle
December 3, 2010

Discussion and Recommendations

Harmonization of Food Ingredients

Discussion

- Issues for food ingredients arise in customs frequently from a lack of harmonization regarding the specifications, grade, paperwork, labeling, etc.
- USDA has recently established a helpdesk for help with “stuck“ shipments that can be contacted via phone or email. See their website.
- ICH has been an effective instruments for drug harmonization. Progress in its Pharmacopeial Discussion Group (PDG) has been accelerated with the involvement of IPEC. In the future, PDG’s work could focus more on excipients and food ingredients.
- USP’s performance-based monographs may be a useful tool for increasing consistency among food standards.
- Government funding may be available for projects aiming at reducing technical barriers to trade.

Harmonization of Food Ingredients

Recommendations

- ICH recommendations for metal impurity limits should be considered when establishing limits for foods. A workshop might be helpful. Methods for metal impurity measurement should be evaluated for appropriateness in food ingredients, and good science should be emphasized.
- Manufacturing for food ingredients and excipient often overlap; the corresponding specifications can be specific to their use as either foods or excipients.
- Harmonization will lower costs by minimizing the number of tests required to demonstrate compliance.
- International specifications, not just those of US, EU, and Japan, should be considered.
- International compendia such as the *FCC* can help in harmonizing globally.

Nanotechnology

Discussion

- Dispute over a definition for nanotech may hinder progress, although definitions have already been established in some cases (e.g., Europe).
- Criteria for characterization of nanotech materials need to be determined case-by-case, particularly for food ingredients.
- The upcoming FDA Guidance addresses amongst others impurities from specific manufacturing processes. Future regulation is likely to address specifications for size.
- Nanotechnology is blurring the lines between foods, dietary supplements, and drugs. Articles and their claims have to be addressed on a case-by-case basis.
- Dec 7 – EFSA discussion on food safety guidelines, which will then be published for global public comments for six weeks. Study data framework alignment is also very important to EFSA.

Discussion (continued)

- A lack of reporting of material grades may result in misapplication of published results.
- It is not understood how nanotech products will be embraced in the marketplace. Proper communication to consumers will be critical. The timeframe for developing communication strategies for nanotechnology is long-term.
- EFSA focuses solely on science. Factors other than science, such as culture, affected the acceptance of GMOs in Europe. It is hoped that a better alignment can occur with nanotech.

Nanotechnology

Recommendations

- Once consensus has been reached on which are the important features to measure in nanoparticles, standardized test methods would be useful.
- A clear definition of nanotech material is elusive but would be beneficial, as long as development of a definition doesn't hinder progress.
- A framework for reporting study data in consistent ways is necessary, especially regarding the characterization of the nanotech materials used.
- International collaboration is important.
- Partnership between suppliers and food companies would be helpful in promoting nanotech products.

Nomenclature

Discussion

- Nomenclature for nanotech articles whose function does not depend on particle size may not require differentiation. Distinguishing in general may not help consumers. Naming internal to FDA may be differentiated.
- Official names for food ingredients in CFR can be changed via petition to FDA.
- Harmonization of nomenclature among articles that can be used as excipients (in some cases even as drugs), foods, and dietary supplements is an issue for USP.
- If variants within a family of compounds (e.g., chemically modified cellulose) are named as a family for labeling convenience, their specific identify may be lost.

General *FCC* Updates

Discussions

- USP's Toxicology Expect Committee will consider proposals for provisional standards to ensure that the self-affirmed GRAS assessment is performed according to scientific standards sufficient for inclusion of this food ingredient in the *FCC*.
- USP plans to make its database of adulteration in food available through publishing it in a scientific journal and/or the *FCC*. The database summarizes scientific publications regarding adulterations in food from the last two to three decades.