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**Food Ingredients Stakeholder Forum
Meeting 2
Wednesday, February 20, 2008
Spalding Auditorium
USP Headquarters, Rockville, Maryland**

Mr. Christopher C. DeMerlis, IPEC, Chair

Discussion and Actions

The 2nd meeting of the Food Ingredients Stakeholder Forum (FI SF) was chaired by Christopher C. DeMerlis, representing IPEC. The following highlights the discussion and the resulting action items for both USP and stakeholders, as noted. The meeting was called to order at 8:00 a.m.

Note: This document, plus the speakers' slide presentations, will serve as the record of the meeting.

Topic 1 - Opening, Welcome, and USP Updates

1a - Meeting Purpose/Goals, Opening Remarks

Mr. DeMerlis greeted and welcomed meeting participants. Mr. DeMerlis thanked the Food Ingredients Expert Committee for its work on the *Food Chemical Codex (FCC)*. He stated the goals and opportunities of FI SF and reviewed meeting briefing materials. He then turned the meeting over to Dr. Roger Williams.

1b - Opening Remarks, USP Updates

Dr. Williams welcomed meeting participants and indicated that in the course of the meeting they will participate, with USP staff, in the celebration of the 6th edition of *FCC*. USP staff, FI EC and the stakeholders all worked together to bring this edition into being, carrying on the work of National Academy of Sciences and Institute of Medicine. Dr. Williams also provided a brief overview of USP emphasizing its non-governmental status. He said he was delighted to conduct this meeting in the new building, which will be formally inaugurated during the first week of March 2008.

Dr. Darrell Abernethy extended a sincere welcome to all participants. He explained the roles of several groups of USP employees who focused on many aspects of the 6th Edition of *FCC* and recognized their work by asking them to stand. Dr. Abernethy also recognized the work of FI EC and commented that its members are teaching USP about foods, as foods are different from drugs. In conclusion he commented that USP's commitment is to continue to publish the best *FCC*.

1c – The FCC Sixth Edition compendia was unveiled. The official release date is February 29, 2008.

Topic 2 - Food Chemicals Codex (FCC) Sixth Edition

2a - FCC 6 Overview

Dr. Jim Griffiths' presentation focused on *FCC* contents. He also provided an example of *FCC* revised monograph and indicated that the next steps would be the release of the 1st Supplement to *FCC 6*, June 2008 *FCC Forum* and *FCC 7*.

2b - FCC Online Demo

Ms. Linda Guard provided a *FCC* online demonstration.

Discussion

- **How much is the online FCC?** The cost is \$595 for each user up to 10, with a discount for each additional user.

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- **It is time-consuming to find formulas in monographs; is there a place to search for formulas?** Yes. A user can enter either a formula or a CAS number in the “search” field and find it in a monograph.
- **Does USP provide text support?** Yes. A user can either call USP or send an-email.

2c - FCC Revision Process and FCC Forum

Dr. Jeffrey Moore provided an overview of the *FCC* revision process and *FCC* publication schedule. *FCC* will be a biennial publication, print and online versions. Dr. Moore indicated that March 15, 2008 is the deadline for all new proposals/comments. USP had a number of proposals in 2007 that are going into the First Supplement to the 6th edition. It is an excellent opportunity for all stakeholders to provide comments.

Discussion

- **Will individual stakeholders be able to go on the website and view/monitor comments?** Yes.
- **Can an e-mail system be set up to notify stakeholders when comments are posted?** USP will explore this possibility. In the interim USP encourages stakeholders to monitor the website under the *Commentary* section
- **Should there be a concern for reduced visibility of FCC because the previous IOM editions were developed under an FDA CFSAN contract and were covered extensively in the Federal Register?** No. USP hopes that there will be even more transparent process, as the *FCC Forum* is available online, free for the public, and easy to navigate. The *FCC* needs to be communicated effectively to the general public as a more streamlined process. Ms. Long made a reference to USP Rules and Procedures, Part 10.01 *Food Chemical Codex*, (d) and (c), *Expedited Standards* and *Immediate Standards*, notices and comments aspect for the expedited standards but not for the immediate standards
- **A participant made an observation that in the past when a new edition of FCC came out, there was much longer lead time before it was considered effective. Would it be a good idea to have a longer lead time?** The *USP-NF* and the *EP* allow a six month implementation time once published. Will a similar approach be used for *FCC*? USP’s decision was guided by the understanding that prior *FCC* editions had been effective when published. The difference between *USP-NF* and *FCC* is that *USP-NF* is legally binding and therefore, sufficient time is allowed for implementation. USP did not think that with *FCC* stakeholders would need such long lead time because of the difference in legal enforceability. This point will be discussed both by the FI EC and the USP management.

2d – Decision-making Process and Transparency

Ms. Angela Long, before she began her presentation, briefly discussed the history of both USP and the *FCC*, and indicated that as part of the new building inauguration on March 4, USP would be naming the various Meetings Center rooms and areas for key leaders of USP. The courtyard will be named after Dr. Justin Powers, a pharmacognosist and the first staff director of the *National Formulary*. Dr. Powers also was a Committee of Revision member and of interest to the FI Stakeholders, he also happened to be the first director of *FCC* until 1966.

During her presentation, Ms. Long explained to the stakeholders USP’s decision-making processes, including transparency in the voting process. She also explained how USP handles commentary for the *FCC*, and how USP Expert Committee meetings also are transparent in that both observers and government liaisons are able to participate.

Discussion

- **How are USP Expert Committees formed?** USP is beginning the process for the 2010-2015 cycle. The USP Convention meets every five years and elects a new Council of Experts, who are the chairs for the Expert Committees. USP will start the recruiting



process in the fall of 2008 when a call for candidates will be issued. There also will be a website page where interested candidates/applicants can go file an application. USP also has a pool of candidates for both the chair positions and the Expert Committee positions. The Constitution and Bylaws require USP to run two candidates for each position. An Expert Committee with chair approval can create Advisory Panels beyond the membership of the committee to assist the committee on specific issues or tasks. These Advisory Panels can be formed and/or dissolved at any time based on the committee needs.

- **Is the United States government aware of international opportunities for USP?**
Yes. USP intends that FCC will meet the needs of customers in the US and elsewhere in accordance with the Board of Trustees draft and current strategic plan. USP is working to ensure that volunteer bodies related to USP have good representation from both the US (e.g., FDA) and elsewhere. International stakeholders at this FI Stakeholder Forum include Mr. Matthew Bauder of Health Canada and Dr. Takeshi Kimura of the International Council on Amino Acid Science. USP also relates closely to the work of Codex and USP hopes to increase its interactions in Codex as an NGO. USP wishes to support the excellent WHO and FAO work relative to JECFA.

2e - Marketing Approaches

Ms. Kathy Flanagan indicated that USP has been promoting regulatory and industry recognition of *FCC* globally. An integrated approach is being taken to marketing this compendia, as major market segments have been identified and targeted, including quality assurance, supply chain management, R&D, product stewardship and safety, etc. A series of introductory courses was created by the USP Professional Education group and are available at no charge to current and prospective *FCC* users. USP Account Managers are marketing *FCC* in most regions of the world, and multilingual Customer Service staff will take orders around the clock.

Ms. Laura Provan provided an overview of USP's media outreach and key messages for both the public and legislators. These messages are designed to continue positioning USP as a trusted voice of health science and to foster a climate of wider acceptance of *FCC*.

Discussion

- **Can customers buy either hard copy or electronic version or get a deal buying both?** Currently print and online versions are sold separately. The print version is available for \$495, the online, for \$595. Currently more customers are purchasing the print version, with only 5-15% of the customers purchasing the online version. USP is adopting a new model; instead of selling the *FCC* book and the supplement separately, it is selling the *FCC* as a subscription. Customers get both the book and the supplement for one price.
- **It would be helpful if USP established a customer base so that stakeholders could get information quickly.** That is being examined via the *FCC* web-page and e-mail alerts.

2f – Education

Mr. Gouker briefed participants on the goals and formats of USP Professional Education. The USP Professional Education series of *FCC* webinars are offered free and are being widely advertised.

2g – Summary

Dr. Williams commented that there is a private and a public concept to the *FCC*. It is important to note that any manufacturer can take an *FCC* monograph and incorporate it into its own SOPs, which is one of USP's goals. In private SOPs, companies can reference *FCC* 1 through 5, but this private reference should not be confused with USP's intent. If a company puts *FCC* on its label to reflect a standard, there is only a current standard, and USP would not wish manufacturers to use the *FCC* label unless the 6th edition and applicable revisions were referenced. Stakeholders



indicated that there are substantial differences between the *FCC* editions. If a company is to comply with the *FCC*, by law in the United States it has to comply with the edition referenced in the Code of Federal Regulations (CFR), for example, the *FCC* 3rd edition. From USP's perspective, there is only the current *FCC* 6th edition. A 20-year old standard is not USP's current position of what the standard for the article should be. USP sees an advantage to engaging industry and the FDA to resolve some of these problems brought up by the regulatory legality of multiple *FCC* editions. From the market point of view the current *FCC* is very important as its standards are related to international standards, such as WHO and JECFA. While some stakeholders want the phase-in period for *FCC* to be the same as for *USP-NF*, others think that manufacturers are under pressure to upgrade as soon as the *FCC Forum* is released even though the *FCC* and *FCC Forum* are not official in the US. From the regulatory perspective, the FDA resources are constrained so the Agency relies on industry self-regulation. That is where the *FCC* can be very helpful, especially as related to the GMPs. The current standards of *FCC* might also be important in litigation.

Topic 3 - USP Food Ingredients Expert Committee

Dr. Ebert indicated that the *FCC* does not have the same regulatory status in the United States and globally as does the *USP-NF*, but is legally recognized in Canada, Australia and New Zealand. The *FCC* could be efficient in facilitating international communication on food components. Stakeholders should not worry about *FCC* becoming official with the regulatory agencies, but should strive to allow it to become official in the marketplace. Dr. Ebert then presented Food Ingredients Expert Committee work plan.

Discussion

Stakeholders noted that harmonization was not on the Stakeholder Forum agenda, as it is too early in the *FCC* process, but from the industry standpoint and from the global company standpoint, food standards should always be looked at globally. Harmonized standards are needed for practical reasons, and therefore, food ingredients stakeholders should consider how to handle food ingredients harmonization. The FI EC will work with the FI Stakeholders on these issues. USP staff is highly supportive of harmonization, and there are ways to advance harmonization working with appropriate communities both in and outside the US.

Topic 4 - International Update

4a - JECFA

Dr. Paul Kuznesof, consultant to USP for the *FCC* and recently retired from the FDA, commented that an incredible achievement has been accomplished with the production of 6th edition of *FCC*. He then presented a 2008 update on JECFA specifications activity that included the outcomes from the 68th JECFA (June 2007) and the agenda for the upcoming 69th JECFA (June 2008). His talk also addressed the interactions and relationship between JECFA and the Codex Committee on Food Additives (CCFA), the process in which JECFA's agenda is established, and the elements that need to be brought together for a successful meeting.

Discussion

- **Should *FCC* adopt JECFA specifications on flavoring agents?** It was noted that the European Commission had agreed to adopt nearly all JECFA's 2000 monographs for flavouring agents and, in light of the source of JECFA's information, principally FEMA, the question was raised as to whether *FCC* should do the same, considering that *FCC* has only prepared about 400 flavourings monographs.
- **Why is JECFA focusing on flavorings as compared to other food additives?** JECFA is not focusing on flavourings at the expense of evaluating other substances. JECFA gives first priority in setting its agenda to the requests coming from the CCFA.. The CCFA has been asking for the evaluation annually of 150-200 flavouring chemicals ever since JECFA developed an efficient procedure for evaluating them. Moreover, although it might appear to US parties that JECFA's terms of reference restrict it to evaluating only food additives, it should be noted that the term "food additive" in the Codex/JECFA sense is much broader than the legal definition in the United States. Thus, JECFA does evaluate many substances that in the US would be GRAS or color additives, for example. At the same time, many ingredients that are GRAS in the United States



would not fit the Codex/JECFA definition of a food additive, so JECFA would not be evaluating them as *FCC* does. Food oils are good examples. There are many food oil monographs in *FCC*, but not in JECFA.

4b - Codex Alimentarius Commission

Dr. Folmer who is USP's FDA liaison and a member of FDA team of the Codex Alimentarius Committee on Food Additives (CCFA), presented an update on the upcoming 40th Codex Committee on food additives, including Codex organizational structure and its eight-step process.

Discussion:

- **There was a recent Federal Register announcement related to the FDA determination of GRAS, and there were a number of chemicals listed and the terminology used referred to the "suitable for intended use" with the exception of one ingredient, vitamin D, which had an *FCC* reference listed. Can we expect to see more *FCC* references listed in the future and what does "suitable for intended use" mean?** In the future, in regards to other references in *FCC*, as FDA reviews new petitions for food additives, it will add additional references.
- **Would JECFA qualify as a reference? Yes. However, historically, FDA tends to refer to *FCC* first, as FDA is most familiar with *FCC*, not so much with JECFA, and JECFA will evaluate non-published safety data.**

Topic 5 - Monograph-Reference Standards Relationship

5 – Uncertainty, Traceability

Dr. Koch noted that his presentation would be about reference materials and would give stakeholders a view how USP deals with reference materials and the USP Reference Standards development program. **Dr. Williams** emphasized that the value of primary reference materials, which are available to all manufacturers. House standards, if used, can be calibrated to the primary reference material. This way all manufacturers test to the same standard for a procedure. USP's general intent is to have a reference material available for all procedures in *FCC*.

Discussion

- **A stakeholder commented that USP reference materials are backordered for a year. Vitamin A Acetate is an example. Is USP planning to do something about it?** Backorder was a problem in the past. USP has addressed it and 99% of all orders are filled the same day. Backordered standards are rare.
- **What percentage of monographs in *FCC* 6th edition have reference standards incorporated?** About a third.

Topic 6 Food Safety

6a - Regulatory Overview

Ms. Kari Barrett thanked USP for the opportunity to speak at the Stakeholder Forum. She indicated that Food Protection is a new office at FDA. So far, there are two employees, herself and Dr. David Acheson, FDA Associate Commissioner for Foods. Ms. Barrett then presented the changes and challenges to the U.S. food and feed supply as outlined in the FDA food protection plan and also an update on other activities of the FDA Food Protection Office.

Discussion

- **Is there a possibility of having more inspectors on site overseas? FDA is working with China to expand its office there.** FDA is also considering opening offices in other locations overseas.
- **Is the FDA third party accreditation program in place for foreign governments?** Not yet. It is in the early stages. With time, the intent is to work with foreign countries to have greater confidence in their standards and regulatory systems.



- **On the issue of import safety, will the Agency look at the multiple use chemicals that have only one number?** Yes. Working with the customs and importing community, FDA is exploring a range of issues including better identification of products, their registration and whereabouts in the chain.
- **On the issue of better collaboration and more consistency working with the Secretary and third party groups, are there ways to boost consumer confidence in the context of scarce Agency resources** Yes. The major opportunity is for FDA to leverage action with a range of outside partners, and the Agency is planning to work with them. As well, the Secretary has made imported product safety, and in particular food imports, as one of his top priorities.
- **Is there a plan at FDA to reorganize the import office at major U.S. airports, have it centralized in terms of review?** The Food Protection office is looking at how to meet the challenges discussed at this meeting. Resources will be applied in areas of greater risk, where there is the most volume. The Agency is looking for ways to be more flexible in deploying resources but a final plan is not yet available.

6b - Legislative Update

Mr. Chris Jennings recognized Ms. Barrett and her colleagues for the work they are doing. They are the real workers who implement and defend policies and proactively address problems. Industry representatives appreciate this and look forward to help meet and address these challenges. He then presented information about the current debate on healthcare in Washington. Changes are coming, no matter what party is in the office. All of the presidential candidates are open to the government challenges. Senator Clinton pays a lot of attention to the food initiatives. Senator McCain is also very supportive of food industry.

Topic 7 Adulterants/Contaminants in Food Ingredients

7a – Overview, Contaminants

Dr. Rulis (Retired from FDA in 2006 after a 29-year career at FDA. For nine years he was Director of FDA's Office of Food Additive Safety. He now works for Exponent, Inc. as a consultant focusing on regulatory strategies for addressing food chemicals and food ingredient safety issues) presented a brief review of food ingredient safety considerations. For foods, a determination of safety is markedly different from that for drugs—based on population exposure and no-effect levels. While food ingredients usually have wide margins of safety, a concern for contaminants such as heavy metals in them is warranted because even minor amounts of such contaminants, if found in many individual additives, can add up to a significant level of dietary intake.

Discussion

- **Where does the poundage data come from?** FDA subscribes to services through which it gets updates on an annual basis.
- **Is the Delaney clause compatible with “no harm”?** Yes. The Delaney Clause, added by Congress to the Federal Food, Drug, and Cosmetic Act in 1958 is a special case. It forbids the approval of any food or color additive shown to cause cancer in man or animals. This prohibition reflects consumers' concerns about the risk of cancer. Zero risk is in fact the standard for carcinogenic additives; if a food additive is shown to be a carcinogen, FDA cannot approve it.

7b - Heavy Metals, Adulterants

Dr. Abernethy commented that USP is developing a new approach for heavy metals contamination and is planning to consider a common approach across food ingredients, dietary supplements and pharmaceutical ingredients. He then presented USP's position on Heavy Metals.



Discussion

- **Is USP aware of the levels that are already established by other organizations such as California proposition 65 and others?** Yes. And they're consistent with what European groups are establishing as well. USP looks forward to stakeholders' input.
- **The heavy metal limits presented in Dr. Abernethy's slides are given as total micrograms per day. How is it distributed over different foods that may contain heavy metals?** It will be a topic for further discussion. As foods are consumed in large mass amounts, the exposure is quite different than in foods consumed in small amounts. So this too needs to be discussed.
- **If two or four different foods that may have lead in them are eaten during the they, is it decided beforehand if contaminants are going to be limited to ¼ the total so when all of these foods are eaten during the day, consumers will not exceed the per day limit? Or is the daily limit enforced for each food, so that the consumer may then be exposed to a combined consumption that is 4 times or more per day?** These numbers should be thought of in terms of what the total consumption per day should be. These are the issues that need to be discussed.

7c.1 - Melamine

Dr. Moore presented an overview of melamine and melamine-related compounds and USP approaches to address the melamine issue in FCC

Discussion

No discussion followed.

7c.2 - DEG in Glycerin

Due to lack of time, Mr. Lafaver did not present his slides. They are available on the USP website.

Action Items and Closing Remarks

Mr. DeMerlis presented the following hot topics resulting from the Food Ingredients Stakeholder Forum Meeting #2:

1. CFR References
2. Implementation Timing
3. FCC "Mark" What does it mean?
4. Common Nomenclature
5. Harmonization
6. Reciprocity/Concordance with JECFA
7. FI Expert Committee Priority
8. 3rd Party Conformity Assessment
9. Cost-Value-Safety
10. Agency Resources and 3rd Parties
11. Awareness of USP: Congress, FDA, Public, etc.
12. Collaboration with Food Ingredients industry on Heavy Metals
 - Consider inviting Food and Dietary Supplement industry representatives to industry Heavy Metals Project Team

He indicated that there might be a possibility to form a Project Team to work on these hot topics and present them at the next forum.

The next FI Stakeholder Forum chair will represent the Enzyme Technical Association (ETA). The gavel was passed to Mr. Gary Yingling, a consultant to ETA who will assure that an ETA member is represented as chair at the next meeting.



Ms. Long presented an Appreciation Certificate to Mr. DeMerlis for his work as the FI SF chair.

The meeting adjourned at 4:15 p.m.

