International Pharmaceutical Excipients Council
Of The Americas

October 6, 2008

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Subject: FDA Draft Guidance for Industry, Residual Solvents in Drug Products Marketed in the United States, August 2008

Reference: Docket No. FDA-2008-D-0413

Dear Mr. Ouderkirk,

As you know, the implementation of USP's Residual Solvents General Chapter <467> has resulted in numerous deficiency letters from OGD and hence confusion throughout the pharmaceutical industry and its suppliers regarding FDA's expectations. The following comments represent a consolidated set of comments from the following organizations who have decided to form an Industry Coalition for Rational Implementation of USP <467> (Coalition) to express industry's concerns with FDA's implementation of <467>:

- IPEC Americas
- IPEC Europe
- GPhA
- CHPA
- PhRMA
- SOCMA's Bulk Pharmaceutical Task Force

I have coordinated our Coalition response and, although these comments are submitted on IPEC Americas letterhead, they do represent our consolidated Coalition comments. The Coalition partner organizations are looking forward to discussing a number of these issues with FDA at our upcoming meeting on October 10th.

All Coalition partners have consistently supported the inclusion of the ICH Q3C Residual Solvents requirements within the context of USP <467> Residual Solvents. As global companies, we recognize the need and advantages to harmonizing requirements and guidance throughout the three regions of the United States, Europe and Japan. Many of us had already incorporated Residual Solvents requirements for our existing products in Europe many years ago and FDA has been applying ICH Q3C to new drug applications for some time as well. Therefore, the incorporation of these requirements in USP for more general application was timely and appropriate.

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While the Coalition strongly supports the application of ICH Q3C Residual Solvents to all pharmaceutical products marketed in the United States, the manner in which these new requirements are implemented is crucial. The FDA Draft Guidance for Industry, Residual Solvents in Drug Products Marketed in the United States, addresses important implementation details, as does a recent document, "Additional Information", on Residual Solvents from the Office of Generic Drugs. While we agree with the need for guidance, the Coalition is concerned by several differences in approach between these documents and those in the approved ICH Q3C Guideline, especially as it relates to Generic Drugs.

Coalition representatives were speakers and participants in the USP-PDA Conference on Residual Solvents in January 2007. Coalition members were also actively involved in the USP Residual Solvent Project Team in the last few years. The Project Team's main goal was to ensure pharmaceutical manufacturers, and their excipient and API suppliers, were aware of the new USP Residual Solvent requirements and how best to prepare for and address those requirements. Industry requested FDA to provide guidance on numerous occasions so that the industry would be clear on what FDA's expectations would be when <467> would become official on July 1, 2008.

Unfortunately, the current draft guidance was not available to the industry until August 6, 2008, five weeks after the standard came into effect. In addition, the guidance provides minimal direction beyond the commitment by FDA to enforce the new USP General Chapter as stated in the Background/Policy as follows: "Beginning July 1, 2008, FDA will require…..". Since July 1, 2008, the Generic Drug industry has experienced a dramatic increase in deficiency letters and product approval delays in part due to the lack of guidance but also due to the varied approaches in FDA divisions in determining compliance to the standard. This has created chaos throughout the industry.

On August 20, 2008 FDA's Office of Generic Drugs (OGD) published their "Additional Information" document on the OGD website in an attempt to provide some clarification concerning some of the issues that industry had been voicing to them through many channels. This document however actually created much more confusion throughout industry as to what exactly OGD meant in a number of areas. Industry was also not sure why guidance such as this came out in such an informal way without a chance for any public comment. It was apparent from the questions that many companies were getting from OGD reviewers that there were many different interpretations of what to expect within OGD. The confusion was not just on the part of industry.

The lack of timely guidance and agency communication on changes to a high impact general chapter that affects every single commercial and pending product is very troublesome. Therefore the Coalition requests **urgent action** by FDA to prevent unnecessary additional work by both FDA and industry due to divergence from the quality standards already approved and implemented under ICH.

Enforcement Discretion by FDA is requested for **all drug product registrations** (new and pending NDAs and ANDAs) with respect to implementation of <467> until a final revised guidance document is available and consistent interpretation of the guidance document and expectations are clarified and fully understood by industry. We would like to be able to comment on this guidance clarification before it goes into effect. The Coalition would also request that all guidance on this topic be incorporated into the one formal Guidance document that applies to all drugs and that the OGD Additional information document be eliminated.

We appreciate the issuance of the FDA draft Guidance (Guidance) to explain FDA's expectations with regard to these new requirements for existing products. This Guidance is for the most part, consistent with the Coalition's plans to adopt the new requirements. We support the Guidance in these aspects in particular:

- FDA expects that in most cases, an Annual Report can be used to report any necessary changes to comply with USP <467>. This will significantly reduce the number of submissions to the Agency and is consistent with 21 CFR 314.70 and the FDA Enforcement Discretion for Compendial Changes.

- FDA will accept validated analytical procedures other than those included in USP <467>. FDA has correctly recognized that USP <467> methods are not universal and will not work for all materials. The USP General Notices section, Residual Solvents, also allows for the use of "other suitable methods". This issue was discussed at length by the USP Project Team to ensure that the Industry could continue to use methods that were more appropriate for control (some of which were already approved by FDA and in use) and to ensure that proving equivalence to the USP method in this specific case was not an expectation. Since the January 2007 USP/PDA Residual Solvents Conference, FDA has consistently maintained that alternative residual solvent methods are acceptable if they are suitably validated. In addition, 21CFR314.50(d) allows for the use of alternative methods. The Coalition agrees with this approach.

There are, however, a number of critical discrepancies between the Coalition's interpretation of the USP requirements and the Agency's expectations as listed in the Guidance and Additional Information documents.

1. The word "test" is used throughout the Guidance document when discussing the Residual Solvent requirement versus ICH Q3C that requires control of residual solvents. The Draft Guidance implies that only testing of the components can be used by the applicant (or supplier) to show how the drug product complies with the <467> requirements. Pharmaceutical manufacturers should be able to leverage qualified suppliers to minimize testing where other controls are adequate. Testing may not be necessary if suppliers have been properly qualified by auditing, quality agreements, etc. using a robust qualification process so that their certification statements can be used in lieu of testing as

stated in 21CFR 211.84(d)(2).

2. The OGD documents imply that drug ingredient manufacturers must include residual solvent specifications on their Certificates of Analysis (COAs). Ingredient manufacturers may not always have "specifications" for the residual solvents that they feel are adequately controlled by process controls at much lower levels than the limits for Class 2 and 3 solvents. They may instead provide qualified statements concerning the "worst case" levels that could be expected based on their understanding of their process. Sometimes, they may know from this process understanding that the solvents used or generated in their process are adequately removed before the final steps to extremely low levels so they become irrelevant. In these cases, no routine testing for these solvents will typically be done and we do not feel that this should be necessary. Ingredient manufacturer's statements should be allowed in any suitable format (for example, a technical data sheet or official letter specifically describing the residual solvent status of the material) and should be viewed as sufficient to demonstrate that the ingredient would meet residual solvent levels provided that the ingredient manufacturer as been appropriately qualified by the drug manufacturer.

3. Although the Guidance recommends submitting Residual Solvent changes in the Annual Report, it is not clear where control of Residual Solvents should be included in the regulatory filing or where GMP inspections should be used for demonstration of compliance.

4. The Office of Generic Drugs (OGD) "Additional Information" on Residual Solvents is considerably inconsistent with the Guidance and the Coalition's interpretation of USP <467> requirements. There are many terms and sections that need clarification and requirements that go well beyond what is required in ICH Q3C or USP <467>.

5. Details in the Guidance and the OGD "Additional Information" documents are inconsistent with how ICH Q3C has been applied since 1997, and will adversely affect both international harmonization and the compliance status of the many marketed products to which ICH Q3C has already been applied.

Listed below are additional details on each of these points:

1. <u>"Test" vs. "Control"</u>

The Guidance document emphasizes the "testing" for residual solvents versus ICH Q3C that emphasizes <u>control</u> of residual solvents. The ICH Guideline includes limits for Class 1, 2 and 3 solvents that are extremely conservative even at the product level. When those limits are extended down to the ingredient level, they are even more conservative.

ICH Q3C provides a risk-benefit assessment for the control of residual solvents. The persistent use of the word "test" in the Guidance document is inconsistent with this approach. Appropriate knowledge about the process and ingredients used is critical to this risk assessment. ICH Q3C recognizes this and provides options for ensuring the product will meet the safety limits.

The focus of ICH Q3C is on the appropriate control of residual solvents at the drug product level. However, there is no recognition in the Guidance document that the requirement is at the drug product level. The USP General Chapter, based on ICH, provides a mechanism for that control by providing certain options.

Note also that the USP General Notices which applies USP <467> requirements to all USP materials, does not use the word "test" but rather states these materials "are subject to relevant control of residual solvents".

We would also like to emphasize the following two paragraphs from the Introduction of the USP <467> Residual Solvents General Chapter:

> *"Testing of drug substances, excipients, and drug products for residual solvents should be performed when production or purification processes are known to result in the presence of such residual solvents. It is only necessary to test for residual solvents that are used or produced in the manufacture or purification of drug substances, excipients, or products.*
>
> *Although manufacturers may choose to test the drug product, a cumulative procedure may be used to calculate the residual solvent levels in the drug product from the levels in the ingredients used to produce the drug product. If the calculation results in a level equal to or below that provided in this general chapter, no testing of the drug product for residual solvents need be considered. If, however, the calculated level is above the recommended level, the drug product should be tested to ascertain whether the formulation process has reduced the relevant solvent level to within the acceptable amount. A drug product should also be tested if a residual solvent is used during its manufacture."*

We recommend a shift in the concept of "testing" to "control" of residual solvents by deleting the words "test" and "testing" and instead retaining the words "requirement" or "control" as the more appropriate terms throughout the Guidance document. In particular, the first paragraph under the first bullet in III.A. was taken out of context and should be rewritten as follows:

> *General Chapter <467> requires control of residual solvents in finished drug products. Although manufacturers may choose to test the drug product, options are also provided for evaluating the active pharmaceutical ingredient and excipient components of the finished drug product for residual solvents. Residual solvent data and/or other qualified supplier information may be used to determine whether the*

finished drug product complies with the limits. If the limits are shown to be met through these options, finished product testing is unnecessary.

In line with the shift from testing to control, rather than expecting to see "detailed data from technical studies and tests", a firm may be able to justify complying with USP <467> through data and/or information gathering from their suppliers to gain a good understanding of their manufacturing process and their controls.

ICH Q3C stresses that the manufacturer should obtain the necessary information from the supplier in order to make a risk assessment for the product. We think that FDA needs to utilize a flexible approach to accepting various types of residual solvent information to demonstrate compliance as long as a good scientific explanation can be made to show that appropriate residual solvent levels are met on the drug product itself.

2. Residual Solvent Specifications on Supplier COAs

The supplier may be able to know that their material meets a certain level of a residual solvent through appropriate process design and controls without having to do any specific testing for the solvents on the ingredient itself. Many suppliers may not have actual specifications for each solvent that potentially may have some residual levels due to its use or generation in the manufacturing process. A specification typically implies that a test may need to be run. However, suppliers may be able to make justifiable claims on their COAs, statement letters or technical data sheets, etc. that their materials will always be less than the limits listed in <467> based on their understanding of their process.

If the residual solvents in an ingredient are present in far lower quantities than the limits listed for Class 2 and 3 solvents, how much verification of this is sufficient for users to accept supplier statements? The term "verification" should be defined to include appropriate supplier qualification efforts primarily involving supplier audits and, where necessary, periodic confirmatory testing. Periodic testing may not always be needed however depending on the level of control demonstrated by the ingredient manufacturer in their process.

This Guidance should allow for this option. This issue was addressed in the recent PQRI project on excipients which was published in Pharm. Tech. in Sept. 2007. FDA was actively involved in this project and supported the use of adequate qualification practices and in-process controls to demonstrate compliance with various test requirements for excipients without having to run tests on the final excipient itself.

3. Residual Solvents Information in the Regulatory Filing

Although the Guidance document recommends submitting Residual Solvent changes in the Annual Report (per section III.A.) or in an Amendment (per section III.C), it is not clear where control of Residual Solvents should be included in the regulatory filing. For example:

The USP <467> Residual Solvent requirement resides at the product level yet there is no location within the regulatory filing to indicate that the product is in compliance with USP <467> if it is not a specific test for the product.

It is not clear where <467> changes should be reported in the filing if an ingredient specification does not change. It is also not clear as to why a change should be reported as in the case where the test for residual solvents is not warranted and this is adequately justified.

It is possible that an ingredient may not meet the limits in USP <467> and the product may still meet the USP <467> requirements utilizing Option 2, for example. It is not clear how to denote these situations in the regulatory filing where ingredients may not meet the limits in USP <467> yet the product does.

In addition, more clarification is needed for Section III. B. Compendial Drug Products Not Approved Under an NDA or ANDA. It is unclear whether FDA wants to be notified in the event that Compendial Drug Products Not Approved Under an NDA or ANDA would not meet USP <467> and if so, what the mechanism would be for that notification.

The Coalition believes that there needs to be clear definition in the Guidance document about what types of information needs to be submitted in Regulatory filing documents at the time of registration vs. what type of information should more adequately be assessed during GMP inspections by the field. We believe that Regulatory filing documents should simply include information stating that the drug product meets the <467> requirements and a basic description of how this is demonstrated. However, the assessment of any of the detailed test data and supplier qualification and certification information used to truly verify compliance to the <467> requirements is something that should more appropriately be assessed as a GMP issue during GMP inspections of pharmaceutical manufacturers.

4. <u>OGD "Additional Information" on Residual Solvents</u>

The Office of Generic Drugs (OGD) "Additional Information" on Residual Solvents is considerably inconsistent with the Guidance and the Coalition's interpretation of USP <467> requirements. The following points should be considered:

- It is important that there be a common approach for all drug products and appropriate and consistent expectations from all of FDA. The Coalition believes the OGD "Additional Information" document provides expectations for complying with USP <467> that are unwarranted and inconsistent with the Guidance and ICH Q3C. Again, as mentioned above in #1, OGD inappropriately stresses the testing for residual solvents rather than the <u>control</u> of residual solvents.

- The OGD "Additional Information" document requires submission of data packages to support residual solvent levels in ingredients and the drug product, whereas, as we agreed with above in #3, the Guidance document more appropriately appears to

expect that the full documentation of compliance should be kept at the manufacturing site for the Agency to review upon request during a site inspection.

- OGD's expectations for submitting compendial method verification packages are inconsistent with prior FDA expectations for compendial methods in general. Again, this should be available upon inspection.

- The OGD Additional Information document states the need for: ***Demonstration that the ingredient/s meets <467> option 1 or option 2.*** This clearly demonstrates an incorrect interpretation of both ICH Q3C and the USP <467> intention. Ingredients themselves cannot "meet <467>" as there are no limits for individual ingredients to meet. The limits and option 1 and 2 only apply to the drug product itself. An ingredient cannot be in compliance with <467> and it seems from some deficiency letters we have seen that FDA has requested that some supplier ingredient COAs state that ingredients meet <467>. All that <467> requires for the ingredients is that the suppliers of ingredients provide information on the residual solvents that are "likely to be present" from use in the manufacturing process or that may be generated in the manufacturing process. <467> provides for the appropriate statements that should be used. However, OGD does not appear to be satisfied with these type of statements even when they state exactly what is listed in <467>. The Coalition wants to know why OGD appears to require ingredient <467> compliance statements and test data as opposed to the kinds of statements specifically called for in <467>.

- Certain expectations for Class 3 solvents in OGD's Additional Information document are inconsistent with the basic premise of ICH Q3C and USP <467> in that Class 3 solvents do not need to be identified or quantified unless they are above the 0.5% limit. There was much discussion during the development of ICH Q3C about the need to identify Class 3 solvents and it was decided that identification of these "safe" solvents was not necessary since the identification of these solvents could negatively impact some component manufacturer's intellectual property protections. There was no need for these solvents to be identified due to their relative safety unless they might be present at fairly high levels.

  OGD has clearly gone beyond the expectations of ICH Q3C and USP <467> by requiring the identification of Class 3 solvents and the Coalition feels that this is **unacceptable**. If, for some reason, OGD feels that they need this information for a particular ANDA they should need to justify to the sponsor why this type of information is necessary on a case by case basis. We would expect that this type of request should be very infrequent.

- For solvents that are not defined as Class 1, 2, or 3, qualification information to support their presence at exposure levels >1.5 µg/day is not in line with the internationally harmonized ICH Q3C and goes beyond the ICH Q3A and Q3B requirements for impurities in drug substances and products.

With respect to limits for residual solvents not defined as Class 1, 2, or 3 and "suitable qualification information", some drug substance and excipient firms are not in a position to supply significant toxicological information. Many of these solvents have been used safely for many years and any toxicology information that might exist is very old. Compliance with the currently approved FDA Inactive Ingredient Guide (IIG) limits should be allowed to be considered as part of the qualification evaluation for excipients to minimize the need for additional toxicology information.

Please reconsider the definition and limit for residual solvents not listed as Class 1, 2 or 3. ICH Q3A (R2) provides another definition of residual solvents that may be more applicable than that in ICH Q3C and USP <467> for these solvents. From this definition it can be concluded that all other detected substances are impurities, even a substance that may be formed intentionally as a by-product, or that may result from a complex manufacturing process, or even storage, yet this substance may be used as a solvent in a different process. The possible limit for such impurities is provided in ICH Q3A and Q3B.

- The exemption for "nonfunctional coating materials, colorants and flavors" is unclear. Perhaps these ingredients are exempt due to their minimal contribution in the formulation. If so, this should be clarified and the types of ingredients should be provided as examples.

  FDA should define what is meant by the term "nonfunctional" coating materials, colorants and flavors. These materials obviously do have some type of function, otherwise they would not be used. Is this meant to mean "immediate release" coating materials, colorants and flavors? The final coating, colorant and flavors are typically present in very small quantities in a drug product and should not require further testing unless the use of these materials would result in a high enough level to become significant. Even then, supplier information on each component of these materials should be allowed to be used to calculate a "worst case" level for the material and this level could then be used in the Option 1 and 2 calculations for the drug product. Testing should not be required unless the use of these materials would result in a high enough level to become significant.

  A very flexible approach is needed here to allow for various ways to demonstrate drug product compliance to <467> when these types of materials are used in the drug product formulation.

  A similar flexible approach should be used to address imprinting inks that may be used since, although the ink may contain solvents as components, the quantity of residual solvent from a printing ink which dries on a dosage form is extremely low. Printing inks themselves usually only contribute a few micrograms to a tablet or capsule and the solvents used fully evaporate during the printing process. Even if all the solvent stayed on the dosage form, it would result in miniscule levels being present that would not impact option 1 and 2 calculations.

5. Consistency with application of ICH Q3C

A key goal of the Coalition in advocating broader adoption of the ICH Guideline on Residual Solvents (Q3C) has been to ensure that the USP requirements are consistent with ICH. After considerable interaction between USP, industry, and FDA, the requirements now effective in USP <467> are consistent with ICH Q3C.

FDA adopted the ICH Q3C Guideline in December 1997 (Federal Register Vol. 62, No. 247) for new product registrations; many products have been approved under this guideline. Some of these products are now subject to USP monographs, and therefore will also be expected to comply with USP <467>. No further implementation steps should be required to comply with USP <467> for these products, beyond those already applied under ICH Q3C. Furthermore, manufacturers should be able to apply the same quality systems, developed to comply with ICH Q3C, to additional products now subject to the improved residual solvents controls in USP <467>.

We request that the Guidance and the OGD "Additional Information" be revised and incorporated into one Guidance document to ensure a smooth adoption of USP requirements, as indicated below.

- In the Draft Guidance clarification is needed in section III,, A. Compendial Drug Products Approved Under an NDA or ANDA:

  Beginning July 1, 2008, FDA will require that U.S. marketed drug products with an official USP monograph (compendial drug products) meet the residual solvents requirements in ICH Q3C Guideline, implemented in USP General Chapter <467> Residual Solvents. Compliance with ICH Q3C Guideline is considered to also constitute compliance with USP <467> Residual Solvents.

- In the Guidance document we would like to request that the following additional point be addressed related to the General Considerations section of the OGD "Additional Information" document,:

  1. USP <467> Residual Solvents applies the requirements of ICH Q3C Guideline on Residual Solvents. Therefore, compliance with ICH Q3C Guideline is considered to also constitute compliance with USP <467> Residual Solvents.

Additional Comments

- With regard to Class 1 solvents, how will FDA handle approved products that contain residual Class 1 solvents that have previously been approved with acceptable levels and not approve other applicants for the same product and suppliers for pending applications? General Chapter <467> recommends that Class 1 solvents should be avoided unless their use can be strongly justified in a "risk-benefit assessment". Data from suppliers indicating the successful removal

of Class 1 residual solvents at the final step of the process to levels below the Class 1 limits, along with a scientifically-sound control program, should be sufficient justification for their continued use where other synthetic routes either do not exist or would require significant changes that could affect the functional properties of the excipient or significantly increase cost. ICH limits for these solvents represent a determination of established safety. Those limits found to be safe as per ICH Q3C should also be regarded as safe relative to USP <467>.

- The Guidance does not discuss the expectations for setting residual solvent limits. ICH Q3C and USP <467> limits are based on safety. In addition, Class 2 and Class 3 limits are based on daily exposure. These limits are not data-driven or process-driven and there is no need to further tighten the limits based on process capability. The setting of residual solvent limits is discussed in the EMEA Note for Guidance on Summary of Requirements for Active Substances in Part II of the Dossier (pages 1 and 2) (http://www.emea.europa.eu/pdfs/human/qwp/029797.pdf) and in the EMEA Quality Working Party Q&As (question #1) (http://www.emea.europa.eu/Inspections/qwp/q12.htm). According to the Q&A, "It has been agreed by the Joint CHMP/CVMP Quality Working Party that there is no need for further tightening of the specification in line with batch results as the limits in the guideline are based on safety assessment."

- Another key point not addressed in the Guidance is the option to support the absence of routine testing of Class 2 solvents in the final API with adequate justification of control and batch data as permitted in the EMEA Annex to the ICH and VICH Guidelines for Residual Solvents (page 5) (http://www.emea.europa.eu/pdfs/human/qwp/045003en.pdf). If FDA were to consider the last two points above in their Guidance, it would significantly contribute to global harmonization efforts.

- FDA OGD reviewers have requested numerous statements from ingredient suppliers to certify that they do not use any solvents that are not listed in <467>. It is clearly an expectation of <467> that a supplier should be supplying information to their customers about all solvents that may be used or generated in their manufacturing process regardless of whether they are listed in <467> or not. Therefore, any statement a supplier makes to their customer about <467> would already include any reference to solvents not listed in <467>. It therefore seems redundant to also require an additional statement certifying that nothing is used that is not on the list. The Coalition feels that these types of certification statements are inherent in any <467> statements issued by suppliers and that these statements should no longer be required because they serve no purpose if the supplier has been qualified adequately.

In summary, the Coalition recommends that:

- The Guidance should be revised to be consistent with ICH Q3C and USP <467> with a shift in focus from testing to control of Residual Solvents.

- The Guidance should permit flexibility with regard to what constitutes suitable verification of supplier statements. This may include verifying that the supplier's COA and regulatory statements are adequate through a suitable supplier qualification/certification program and scientific assessment of residual solvent control in the finished product. This addresses Class 1, 2, and 3 solvents as well as those not designated as being Class 1, 2, or 3.

- It should not be necessary to routinely test for solvents that are not used. In addition, it should not be necessary to routinely test for solvents that, while used, have been shown to be removed by the process to below required levels and, due to early use / processing, are not likely present. A supplier's explanation as to how they have assessed this to understand what may be present should be enough to meet this requirement.

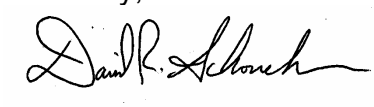
- FDA should provide direction as to where Residual Solvent information should be located in the regulatory filing and what information should be considered as part of filing vs. what type of information should be considered to be GMP compliance information to be assessed during FDA inspections of the site. The Coalition believes that regulatory filings should not contain detailed <467> compliance information and that this type of information should be assessed during GMP inspections. Regulatory filings should simply provide basic information about how <467> is met on the drug product.

- OGD expectations should be brought in line with the revised Guidance document, and both the Guidance and the OGD "Additional Information" should be revised and incorporated into one Guidance document to ensure drug products already approved under the ICH Q3C are not adversely affected.

- **Enforcement Discretion** by FDA is requested for **all drug product registrations** (new and pending NDAs and ANDAs) with respect to implementation of <467> until a final revised guidance document is available and consistent interpretation of the guidance document and expectations are clarified and fully understood by industry. We would like to be able to comment on this guidance clarification before it goes into effect.

I hope these comments can help FDA clarify their requirements to industry related to the implementation of USP <467>. If you have any questions regarding this information, please contact me.

Sincerely,



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