



U.S. Pharmacopeia
The Standard of Quality™

February 3, 2009

The Honorable Barack H. Obama
President of the United States
The White House
Washington, D.C. 20500

Dear Mr. President:

As a private, non-profit, all volunteer, standards-setting body in existence since 1820, The United States Pharmacopeial (USP) Convention helps to ensure the quality, safety, and benefit of food and drugs, working closely in law with the Food and Drug Administration (FDA).

We therefore appreciated the attention you focused yesterday on the important challenges facing FDA in ensuring the food supply is safe for consumers. I would like to share with you a number of recommendations USP has made to Department of Health and Human Services Secretary-Designate Tom Daschle and Acting FDA Commissioner Frank Torti, which we think would help strengthen FDA and help it confront a number of challenges in helping to ensure safe foods and medicines for all consumers.

Under the 1938 Food, Drug and Cosmetic Act, prescription and over-the-counter medicines sold in the United States must comply with quality standards published in USP's book of standards, the *United States Pharmacopeia*. USP also publishes food ingredient standards through its *Food Chemicals Codex (FCC)*.

FDA's and USP's mutual efforts are not only in the country's interest, and support your desire to enhance science as a national priority, but also further conserve FDA's scarce resources in advancing its programs, which are so critical to the nation's health, and so crucial in protecting consumers.

Like FDA, USP recognizes the increasingly global nature of the drug and food supply. Our office and laboratory facilities in our Rockville headquarters and in Europe, China, India, and Brazil are evidence of this commitment to protect consumers—as are FDA's new offices abroad. We have a shared vision to advance consumer health through joint FDA-USP standards-setting activities.

The situation you mentioned with peanut butter and salmonella is deeply troubling. While it appears part of the problem may have been apparent lack of adherence to existing laws, we also do believe legal protections can be strengthened to help ensure the safety of the American consumer.

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The Congress has been considering legislation that would help address the issue of microbial contamination in foods—such as the recent salmonella outbreak and other incidents in the recent past that have occurred with spinach and tomatoes, and we believe those discussions are helpful and constructive.

We recognize that existing Congressional efforts are directed at very specific food safety areas, such as food-borne illness, and measures to combat it, including hazard analysis, risk-based preventative controls, and performance standards directed at the most significant food-borne contaminants. We also hope the Administration and the Congress will consider the threat to food safety caused by adulteration of food ingredients.

Several widely publicized recent incidents illustrate this type of risk; for example, the deliberate adulteration of wheat gluten from China with melamine, which caused significant toxicity in pets, and may also have affected poultry and swine products intended for human consumption. The subsequent contamination of infant formula and other milk-based ingredients in China and other countries has heightened this public concern. We are working closely with FDA to help develop tests that might prevent future incidents of this type of adulteration, and we believe that tightening protection in this area is critical to public health.

The threat posed by adulteration of food ingredients, whether intentional or unintentional, is very real. Today, food ingredients contained in processed foods—including peanut butter, which you mentioned—are a significant part of the American diet. The typical dinner or school lunch plate includes not just meat and produce, but also myriad seasonings, preservatives, and other food ingredients that make up the numerous processed and packaged foods Americans consume. Safe food ingredients are therefore as important to consumers as are safe foods.

Uniform public food ingredient standards can provide assurance that widely used food ingredients are safe, because adherence to those standards helps assure consistently high quality and lack of harmful substances, and can help thwart intentional adulteration. We recognize that adherence to standards for food ingredients is only one piece of an overall food safety solution. However, it is a piece that should not be overlooked.

While USP is best known for setting drug quality standards published in the *United States Pharmacopeia—National Formulary (USP—NF)*, it has also begun setting standards for food ingredients, using the same open and participatory science-based processes used to establish its drug standards. These standards are published in the *FCC*, which USP recently acquired from the Institute of Medicine (IOM) and has now published in its 6th edition. A limited number of *FCC* standards are incorporated into specific FDA regulations approving particular food additives, but unlike the drug standards in the *USP—NF*, *FCC* food ingredient standards do not have broad legal recognition.

We believe greater legal recognition of *FCC* standards would benefit the public by helping to ensure the safety and quality of food ingredients, in the same manner that

recognition of *USP—NF* standards does for drugs. We believe standards of quality, purity, and identity for preservatives, antioxidants, colors, and other substances used as components of food can play an important role in ensuring the overall safety of our food supply.

Although the Secretary has the current authority under the Food, Drug, and Cosmetic Act to set food ingredient standards, and does so as evidenced in 21 CFR Parts 172-189, many of the established food ingredient criteria are now outdated or lacking the detail necessary to provide adequate guidance to the food industry or inspire confidence in the consumer. Relying on available public food ingredient standards such as those provided in the *FCC* allows the government to conserve its scarce resources since the Secretary would not have to develop standards in these areas. Standards published in the *FCC* are updated on a regular basis and can be revised quickly when necessary to respond to public health crises without the need for additional legislation or regulation.

We also note that recognition of existing standards would be consistent both with FDA's Food Protection Plan, which seeks to use private (non-governmental) standards where appropriate, and with the general effort in the federal government over the last decade to recognize existing private standards.

Finally, we note that a number of Congressional proposals require third party certification. Along those lines, USP operates verification programs for drug ingredients and dietary supplements, and we think this could serve as a model for the Congress and the Administration in the area of import safety. USP would be pleased to work with FDA to make our expertise available.

We look forward to being a continued resource to the Administration as you consider these very important issues.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Williams", written in a cursive style.

Roger L. Williams, M.D.
Chief Executive Officer
The United States Pharmacopeia

Attachments



U.S. Pharmacopeia
The Standard of Quality™

January 29, 2009

Frank M. Torti, MD, MPH
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857-0001

Dear Acting Commissioner Torti:

The United States Pharmacopeial Convention (USP) appreciates your commitment to public health and support for science-based regulation of food and drugs. As a non-profit all volunteer standards-setting body in existence since 1820, USP helps to ensure the quality, safety, and benefit of food and drugs, working closely in law with the Food and Drug Administration (FDA).

I note with enthusiasm your interest in enhancing the scientific capabilities and background of the Agency and staff in day-to-day decision-making and in establishing partnerships that leverage FDA resources—important goals to protect consumers and patients in the face of sophisticated technological change, new potential threats, and the globalization of product and ingredient manufacturing.

Like FDA, USP recognizes the increasingly global nature of the drug and food supply. Our office and laboratory facilities in our Rockville headquarters and Europe, China, India, and Brazil are evidence of this commitment to protect consumers—as are FDA’s new offices abroad. We have a shared vision to advance consumer health through our joint FDA-USP standards-setting activities.

Along those lines, we make the following recommendations for even closer FDA-USP cooperation, and attach recommendations this organization has shared with Secretary-Designate Daschle.

1. Strengthening the FDA-USP Relationship

USP produces two official compendia of the United States that are recognized in the Food, Drug and Cosmetic Act (Act) and are legally enforceable by the FDA. These are the *United States Pharmacopeia (USP)* and the *National Formulary (NF)*. USP also produces national primary reference materials (official USP Reference Standards)—vials of chemical and biological materials used to test conformity to these documentary standards—that are closely allied with the procedures of the monographs in the compendia.

In addition to standards for drugs, which are enforceable under both the adulteration and misbranding provisions of the Act, these compendia include documentary standards for dietary supplements recognized under the misbranding provisions of the Act. USP also publishes standards for food ingredients (with allied reference materials) in the *Food Chemicals Codex*, which USP obtained from the National Academy of Sciences in 2006.

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Over many years, USP has worked closely and productively with FDA. Our partnership has endured for a century in the Federal Food, Drug, and Cosmetic Act. Specifically, *USP-NF*'s status as official compendia in that Act helps protect the public by enabling USP to set robust and widely respected standards for drug quality working closely with FDA and other regulatory and enforcement authorities. The adulteration provisions in the Act allow FDA to remove rapidly a drug (including a biologic) that does not meet USP's compendial standards of strength, quality, and purity.

USP believes this relationship can be further strengthened to provide even more assistance to FDA in critical areas related to drug and food ingredient quality, supply chain management, import safety, critical path initiatives, and harmonization.

2. Saving FDA Critical Resources

FDA's and USP's mutual efforts are not only in the country's interest, and support the President's desire to enhance science as a national priority, but also further conserve FDA's scarce resources in advancing its programs, which are so critical to the nation's health, and so crucial in protecting consumers.

Specifically, USP helps the Agency save resources in written (documentary) standards development with allied reference materials (national primary standards) that protect the public through our joint USP-FDA standards-setting and related initiatives.

Public standards and the availability of related national primary reference (physical) materials help to strengthen the safety net and protect consumers. Many of USP's standards also provide validated methods useful in private regulatory filings and thus save not only manufacturers but also FDA review staff considerable resources related to the submission and review processes.

We would like to continue to work with FDA to identify ways to advance work in this area.

3. Together Protecting Consumers

Consumers depend on FDA to enforce USP's standards, and consumers and patients are the ultimate beneficiaries of these efforts. Industry also benefits from USP standards by having a clear pathway and safe harbor to avoid a charge of adulteration.

USP standards help promote the quality and consistency of drug products worldwide so that consumers can have confidence that their medicines are 'what the doctor ordered', and that foods, including dietary supplements, have requisite safety and quality. Up-to-date public standards for medicines, food ingredients, and supplements are critical in protecting the public's health and safety—particularly important in the context of import safety, and discussions about adulteration and contamination.

Whether at FDA's request or on our own initiative, USP has demonstrated the long-term commitment and ability to update and create new documentary standards and associated chemical and biological reference materials that help assure drug and food quality and safeguard public health. Our standards are set after careful scientific review, through a rigorous and public process that involves volunteer technical experts and input by FDA.

As circumstances necessitate, USP moves quickly to create revised or new standards in response to newly emerging public health threats (as with heparin, glycerin, and melamine). Working in partnership with FDA, USP sometimes can effect these changes more rapidly than is possible through government regulatory action. For example, as a result of specific requests from FDA, early next month we will announce even tighter standards for heparin and glycerin. We look forward to building upon and enhancing these consumer protection efforts.

In addition, our verification programs for drugs, drug ingredients, and dietary supplements (<http://www.usp.org/USPVerified/>) could serve as a model for FDA and the Congress in discussions on import safety. Verification programs can help assure consumers a manufacturer has met rigorous voluntary standards for quality and purity, and can also preserve scarce FDA resources. We would welcome the opportunity to discuss these programs with you and be an active resource in this area.

4. Offering Our Scientific Expertise to Advance Standards

We can also offer FDA our scientific expertise and work on technical standards for drug quality, food ingredient quality, biologics, and a host of other topics. This expertise reflects the broad and deep scientific and technical experience in USP's core standards-setting body, the Council of Experts. This includes our Expert Committee and Advisory Panel members, which in total number 124 individuals, drawn from 31 countries (<http://www.usp.org/pdf/EN/members/COEReport.pdf>), and who are included among the 720 volunteers who contribute their expertise.

USP's core sciences are focused on measurement science (metrology), which is closely allied with manufacturing science. Manufacturing science undergirds many of the Agency's initiatives under the general term "Quality by Design."

We could work more closely with FDA on many other key science topics, including an important one now that may promote compendial harmonization. This topic relates to 'equivalent or better' statements that allow FDA to rely on suitable procedures maintained in private regulatory filings and in other advance compendia.

In summary, there are a number of areas where we can deepen our already strong relationship. We stand ready to be of assistance. I would welcome the opportunity to meet with you briefly to discuss the possibilities, and can be reached at 301-816-8300 or rlw@usp.org

Sincerely,



Roger L. Williams, M.D.
Chief Executive Officer
The United States Pharmacopeial Convention

Attachment

Making the FDA More Effective: Top Six Recommendations from the US Pharmacopeia, a Public Health Non-Profit

- 1. Increase Funding for FDA.** The United States Pharmacopeial Convention (USP) joins a broad range of other consumer and healthcare organizations that have urged the incoming Administration to work with Congress to increase funding for the FDA. This increase is critical to ensure the agency can carry out its public health mission more effectively. The February 2008 report of the FDA Science Board's Subcommittee on Science and Technology makes specific recommendations for increased funding. Organizations such as the Alliance for a Stronger FDA, of which USP is a member, the American Heart Association, the American Red Cross, the National Consumers League, and the National Organization for Rare Disorders, as well as industry representatives in the drug and food arena have called for greater funding. *Failure to give the FDA these resources jeopardizes the Obama Administration's ability to achieve its broad health care quality goals* as well as the broader public health and safety—and could have negative economic impacts on the nation.
- 2. Ensure New FDA Commissioner Has a Strong Scientific Background.** The single most important drug and food safety decision facing President Obama is the appointment of a top-notch, respected FDA Commissioner who is viewed as independent, informed, and fair-minded. *It is crucial that the new Commissioner has the scientific background needed to make informed decisions* on increasingly complex issues facing the agency, including those dealing with drugs, foods, dietary supplements, biologics and healthcare quality. Greater independence also could be gained by making the Commissioner a 6-year appointment.
- 3. Strengthen the Science Base of FDA's Decision-Making.** In addition to ensuring that the FDA Commissioner has a premier science background, agency managers must have greater access to scientific expertise in all of their decision-making. This requires an expanded science staff and capability to better solicit, receive, and digest unbiased technical information in making regulatory decisions. This could include making better use of the National Academy of Sciences and USP, which already assists FDA. For new drugs, we suggest a stronger focus on the risk assessment—the process of identifying the probability of harmful effect.
- 4. Expand the Use of Standards in Drug and Food Quality.** Because of the success of USP's historical partnership with the FDA in setting standards under the Food, Drug, and Cosmetic Act, and the legal recognition of USP's official standards for drugs, we believe strongly that the agency should place much greater emphasis on the role of public standards and associated technical aids (e.g., chemical reference materials used by producers and regulators). This will provide greater assurance of drug and food quality. Standards are critical to FDA's regulatory role, and should undergird FDA's decision-making-- affecting people, processes, and products.

Recent examples include USP's cooperation with the FDA by developing updated standards for heparin and about-to-be released standards for glycerin. These standards plug holes in the safety net by establishing tests and other procedures that drug and other manufacturers legally have to follow under the Food, Drug, and Cosmetic Act, to ensure the adulterant is not present, and which help protect the public. These standards will help prevent deaths and severe illnesses in the future.

Our joint work on melamine is another example; we are working on tests that should help prevent melamine contamination and illness or death. This science-based work complements FDA efforts to identify and prevent high nitrogen contaminated products such as melamine from entering the U.S. market.

In all these cases, failure to protect the public from these adulterants could have a disastrous public health consequence, as we saw most recently in the case of contaminated infant formula, overseas. It is important that we work to avoid or minimize the next public health crisis, whether caused accidentally, or intentionally through acts of counterfeiting or terrorism. Failure to address these areas would make the FDA—and the American public—vulnerable.

There are areas where the FDA should work more closely with standards-setting organizations (such as USP, the Commerce Department's National Institute of Standards and Technology, and the American National Standards Institute) to 1) fill gaps in existing compendia of standards and associated technical aids, and 2) increase recognition of standards in ways beneficial for public health and for the United States USP's compendia of standards could bring national uniformity to all food ingredients and drugs, conserving FDA's resources while improving public health and safety.

These collaborative efforts could include third-party verification. While there are a variety of viewpoints about the best way to ensure imports are safe, current public standards and USP's still nascent verification programs might provide a useful model for FDA and the Congress, if the appropriate statutory framework is developed. This also might assist FDA in an era of scarce resources. USP stands at the ready to offer our expertise and assistance in this area.

5. Ensure that Decisions on Biogenerics are Science-Driven.

USP is available as a scientific resource to the Secretary and the Congress as decisions are made on policies and actions in biogenerics. Recent proposals in Congress would amend the Public Health Service Act (PHSA) to create a regulatory pathway for follow-on biologics (FOBs, or so-called "biogenerics"). Such legislation is viewed by many, but not all, as necessary in light of both scientific challenges related to obtaining FDA approval of biologics that are deemed similar or identical to previously-approved biologics, as well as historic complexities involving legislative mechanisms for the approval of biologics under the PHSA and the Food, Drug, and Cosmetic (FD&C) Acts. If a FOB were approved, USP would develop or revise monographs as we do for other drugs (including FD&C Act biologics). We have analyzed the law and believe we would have authority under PHSA, as we do under FD & C.

6. Promote Science-Based Regulatory Outreach to the International Community.

Regulators overseas are eager to know what FDA has to say on a host of drug and food quality and safety issues, and the FDA should enhance its activities in this arena. The new Commissioner should reach out to the international community, starting with the WHO and then advancing to key countries and regions (China, India, Brazil, Russia, ASEAN, Europe). The Commissioner should assess the effectiveness of the International Conference on Harmonization (ICH) and also enhance work with other nations' drug control laboratories. Failure to act in this area could reduce the United States's competitiveness and standing in the world, since it is important that we communicate with customers and regulators who might adopt our standards.



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January 29, 2009

The Honorable Tom Daschle
Secretary-Designate
Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C., 20201

Dear Secretary-Designate Daschle:

Congratulations on your nomination as Secretary of the Department of Health and Human Services (DHHS). The United States Pharmacopeial Convention (USP) appreciates your commitment to public health. As a non-profit organization that helps to ensure the quality, safety, and benefit of medicines and foods, we look forward to working with you. We have a long, productive history of assisting the Food and Drug Administration (FDA), which is a member of our organization.

With the renewed national focus by the Obama Administration in protecting public health, USP can be a valued and trusted resource to you and your staff, and we offer our services and expertise in any way that would be helpful.

The primary way in which we could do that is by providing to FDA our scientific expertise and technical standards in the areas of drug quality, food quality, and biologics. These topics will be very important for the Administration in the context of food and drug safety – including import safety, healthcare reform, and other important national priorities.

We also offer several suggestions with respect to the FDA, specifically:

- The importance of increasing funding for FDA.
- The role of science, both in selecting the Commissioner and agency decision-making—including the idea of making the Commissioner a 6- year appointment to further the Commissioner’s independence.
- The centrality of public standards in FDA’s activities, and recommended areas for cooperation with standards-setting organizations.
- The need to for FDA to work more closely with the international community.

USP has a close relationship with FDA, having worked for a century in a partnership now recognized in the Federal Food, Drug, and Cosmetic Act. Specifically, *USP-NF’s* status as an official compendium under that Act helps protect the public by enabling USP to set robust and widely-respected standards for drug quality working closely with FDA and other regulatory and enforcement authorities. FDA is critical to the nation’s health, and its importance in protecting consumers cannot be overstated. USP looks forward to enhancing and strengthening that relationship.

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At FDA's request, or initiated on our own, USP has demonstrated the commitment and ability to update and create new documentary (written) standards and associated chemical and biological reference materials that are used to help assure drug and food quality and to safeguard public health. Our standards are set after careful scientific review, through a rigorous and public process that involves volunteer technical experts. Some of our standards are developed in response to newly emerging public health threats. Those include our recent work to avoid intentional or accidental adulteration (heparin, glycerin, and melamine) or accidental reasons. As a result of specific requests from FDA, early next month, we will announce even tighter standards for heparin and glycerin. Working in partnership with FDA, USP sometimes can initiate these changes more rapidly than is possible through government regulatory action.

Consumers depend on FDA to enforce USP's standards, and consumers and patients are the ultimate beneficiary of these efforts. Industry also benefits by having a clear pathway to the U.S. market, and from increased levels of consumer and practitioner confidence. USP standards help promote the quality and consistency of drug products worldwide—so that consumers can have confidence that their medicines are 'what the doctor ordered.' Up-to-date public standards for medicines, foods, and supplements are critical in protecting the public's health and safety—particularly important in the context of import safety, and discussions about adulteration and contamination. An even closer USP-FDA partnership can make this possible.

Again, USP offers warm congratulations on the road that lies ahead. We stand at the ready to be of assistance.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Williams', with a long horizontal flourish extending to the right.

Roger L. Williams, M.D.
Chief Executive Officer
The United States Pharmacopeial Convention

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- 2. Ensure New FDA Commissioner Has a Strong Scientific Background.** The single most important drug and food safety decision facing President Obama is the appointment of a top-notch, respected FDA Commissioner who is viewed as independent, informed, and fair-minded. *It is crucial that the new Commissioner has the scientific background needed to make informed decisions* on increasingly complex issues facing the agency, including those dealing with drugs, foods, dietary supplements, biologics and healthcare quality. Greater independence also could be gained by making the Commissioner a 5- or 6- year appointment.
- 3. Strengthen the Science Base of FDA's Decision-Making.** In addition to ensuring that the FDA Commissioner has a premier science background, agency managers must have greater access to scientific expertise in all of their decision-making. This requires an expanded science staff and capability to better solicit, receive, and digest unbiased technical information in making regulatory decisions. This could include making better use of the National Academy of Sciences and USP, which already assists FDA. For new drugs, we suggest a stronger focus on the risk assessment—the process of identifying the probability of harmful effect.
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There are areas where the FDA should work more closely with standards-setting organizations (such as USP, the Commerce Department’s National Institute of Standards and Technology, and the American National Standards Institute) to 1) fill gaps in existing compendia of standards and associated technical aids, and 2) increase recognition of standards in ways beneficial for public health and for the United States USP’s compendia of standards could bring national uniformity to all food ingredients and drugs, conserving FDA’s resources while improving public health and safety.

These collaborative efforts could include third-party verification. While there are a variety of viewpoints about the best way to ensure imports are safe, current public standards and USP’s still nascent verification programs might provide a useful model for FDA and the Congress, if the appropriate statutory framework is developed. This also might assist FDA in an era of scarce resources. USP stands at the ready to offer our expertise and assistance in this area.

- 5. Ensure that Decisions on Biologics are Science-Driven.** USP is available as a scientific resource to the Secretary and the Congress as decisions are made on policies and actions in biologics. Recent proposals in Congress would amend the Public Health Service Act (PHSA) to create a regulatory pathway for follow-on biologics (FOBs, or so-called “biogenerics”). Such legislation is viewed by many, but not all, as necessary in light of both scientific challenges related to obtaining FDA approval of biologics that are deemed similar or identical to previously-approved biologics, as well as historic complexities involving legislative mechanisms for the approval of biologics under the PHSA and the Food, Drug, and Cosmetic (FD&C) Acts. If a FOB were approved, USP would develop or revise monographs as we do for other drugs (including FD&C Act biologics). We have analyzed the law and believe we would have authority under PHSA, as we do under FD & C.
- 6. Promote Science-Based Regulatory Outreach to the International Community.** Regulators overseas are eager to know what FDA has to say on a host of drug and food quality and safety issues, and the FDA should enhance its activities in this arena. The new Commissioner should reach out to the international community, starting with the WHO and then advancing to key countries and regions (China, India, Brazil, Russia, ASEAN, Europe). The Commissioner should assess the effectiveness of the International Conference on Harmonization (ICH) and also enhance work with other nations’ drug control laboratories. Failure to act in this area could reduce the United States’s competitiveness and standing in the world, since it is important that we communicate with customers and regulators who might adopt our standards.