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# Franck's Lab Case Draws Bright Line Between Guidance and Regulation

By [Dan Schiff](#) / [Email the Author](#) / [Health News Daily Jan. 24, 2012](#)  
Today's Stories / Word Count: 845 / Article # 29120124003

## Executive Summary

FDA lost a federal case in Florida over the “‘maximalist’ interpretation of its authority.” The outcome of the Franck’s Lab case could have broad implications for the agency’s use of sweeping guidance documents, such as last year’s new dietary ingredient notification draft.

A recent court decision that came down against FDA’s use of a guidance document in enforcement could have broad implications for the agency’s use of guidances, attorneys say.

Some experts question whether FDA violates the Administrative Procedure Act and its own statutory authority by promulgating sweeping process changes by guidance document rather than notice-and-comment rulemaking – last year’s new dietary ingredient notification draft guidance being a prime example.

In September, the U.S. District Court for the Middle District of Florida ruled that FDA did not have the authority to enjoin Franck’s Compounding Lab from compounding animal drugs. Partially at issue was a controversial 2003 guidance document on animal drug compounding, issued in final form with no comment period, that FDA used as a basis for regulating state-licensed veterinary pharmacy compounding ([“FDA Guidance Policy Could Be Hurt By Ruling On Animal Drug Compounding” — “The Pink Sheet,” Sep. 26, 2011](#)).

The court concluded the Food, Drug and Cosmetic Act does not support the agency’s “‘maximalist’ interpretation of its authority.”

## Global Impact At FDA

Though the government appealed the decision in November, FDA has more than the court’s judgment to contend with. Notably, during the district court proceedings, the agency’s own former chief counsel Sheldon Bradshaw submitted a declaration opposing FDA’s motion for preliminary injunction.

“I do not know why FDA failed to follow” its good guidance practices with regard to the animal drug compounding guidance that went straight to final form, wrote

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Bradshaw, the chief counsel from 2005 to 2007 and now a partner with Hunton & Williams.

"In my opinion, the agency's failure to do so calls into question the validity of that document's guidance," he added.

FDA's good guidance practices final rule, published in September 2000, takes pains to delineate laws and regulations from guidance documents, which only represent the agency's thinking on a matter.

Further, FDA told stakeholders it is "committed to ensuring that you have the opportunity to participate in guidance document development as much as possible" and clarified a willingness to withdraw and reissue controversial guidances.

Guidance documents that generate minimal controversy tend to concentrate on specific, technical areas in need of clarification. FDA's guidance on dosage delivery devices for oral liquid OTCs, issued in draft form in November 2009 and finalized May 2011, is an example of a narrowly focused guidance (["In Brief" — "The Tan Sheet," May 9, 2011](#)).

A Washington Legal Foundation backgrounder says the outcome of the Franck's Lab case could affect how all FDA centers use the guidance mechanism.

"If upheld on appeal, the Franck's Lab decision will be invoked by interested parties seeking to constrain FDA's use of non-binding guidance documents to define prohibitions against which FDA may take enforcement action or impose new requirements on applicants," write Karla Palmer and Jeffrey Gibbs of Hyman, Phelps & McNamara, in the Dec. 15 backgrounder.

## Weighing Economic Impact

Since the NDI notification draft guidance emerged in July, several attorneys have said FDA's expectations for notifications go so far beyond the language of the Dietary Supplement Health and Education Act, a proposed regulation would have been more appropriate (["FDA NDI Notification Draft Guidance Contradicts Final Rule – Ullman" — "The Tan Sheet," Aug. 15, 2011](#)).

Anthony Young of Kleinfeld, Kaplan & Becker says the NDI notification paradigm laid out in the guidance, like current good manufacturing practices for supplements, will have substantial economic impact on companies in the industry. But as a final rule subject to APA, GMPs were vetted by the Office of Management and Budget to present a clearer picture of that impact and allowed feedback from stakeholders (["GMP Cost Impact, Ephedra Suits Loom Over Supplement Industry – Israelsen" — "The Tan Sheet," Apr. 3, 2006](#)).

For supplement makers, unlike the pharmaceuticals industry, meeting regulatory requirements beyond basic safety assurances adds costs without increasing market value, said Young, who also serves as general counsel to the American Herbal Products Association.

"The impact of all that has a different economic analysis when you evaluate what the draft guidance does. So to me, that strengthens the argument [that] guidance – with the number of substantive impacts found here – should be done by regulation," he added.

Daniel Fabricant, director of the Division of Dietary Supplement Programs in FDA's food center, has emphasized the NDI notification guidance remains a draft and will not serve as the basis for agency enforcement. The division has begun sorting through more than 7,000 public comments on the document.

Scott Bass, a partner with Sidley Austin, said as long as FDA refrains from enforcing against companies not submitting NDI dossiers in line with the draft guidance, the agency stands on solid legal ground. But that doesn't mean Fabricant and staff don't have a lot of editing ahead of them before offering a final document, he added.

"The draft guidance has many parts that are logical and some that are very overreaching and improper," Bass said.

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