

## **FDA Issues Final Ruling on Ephedra**

### **Regulation Bans Sales of Supplements Effective April 12; "Traditional Asian Medicine" Exempted**

By Editorial Staff

The Food and Drug Administration has issued a final ruling prohibiting the sale of dietary supplements containing ephedrine alkaloids because, in its estimation, such supplements present an "unreasonable risk of illness or injury" to the general public.

The complete 263-page rule was published in the *Federal Register* Feb. 11, and becomes effective April 12, 60 days from the date of publication.

"This FDA rule reflects what the scientific evidence shows - that ephedra poses an unreasonable risk to those who use it," remarked Health and Human Services Secretary Tommy Thompson. "The regulations prohibit the sale of dietary supplements containing ephedra, and we intend to take swift action against anyone who puts consumers at risk by continuing to sell such products after the prohibition takes effect."

In traditional Chinese medicine, ephedra - also known as *ma huang* - has been used for thousands of years, primarily to relieve colds and treat conditions such as asthma and edema. When taken in the proper dosage, combined with other herbs, and used under the care of a licensed acupuncturist or doctor of Oriental medicine, ephedra is considered quite safe. In the United States, however, the herb has been marketed as a major component of weight-loss pills and formulas, and in the past decade, it became a favorite among people trying to shed extra weight or enhance athletic performance. By the year 2000, ephedra became one of the most popular herbs in the country, generating approximately \$1 billion in annual sales.

As ephedra increased in popularity, several private agencies, particularly sports organizations, began restricting or banning its use. In 1997, the National Collegiate Athletic Association banned the use of all

ephedra-containing products. (Ephedrine had previously been banned by the International Olympic Committee and the United States Olympic Committee.) Between 1999 and 2003, additional bans on ephedra were instituted by the National Football League, National Basketball Association and Major League Soccer. In 2002, the U.S. military banned the sale of ephedra from all post exchanges after a report attributed the deaths of approximately 30 servicemen to ephedra-containing supplements.

Following the death of Baltimore Orioles pitcher Steve Bechler in February 2003, state legislatures began drafting laws to ban or curb the sales of ephedra. On May 25, 2003, Illinois became the first state in the U.S. to ban the sale of ephedra supplements. New York and California quickly followed suit; however, the laws in those states included exemptions that allowed for ephedra to be dispensed by licensed acupuncturists and doctors of Oriental medicine.

The first serious federal action toward ephedra took place in June, 1997, when the FDA issued a proposal requiring that dietary supplements containing ephedrine alkaloids include a warning that they are hazardous and should not be used for more than seven days. It also proposed to restrict the amount of ephedrine alkaloids in supplements. In February 2003, the agency announced a series of measures that included taking action against firms that made unsubstantiated claims about products containing ephedra and enhanced athletic performance. The following month, it published a notice in the *Federal Register* seeking public comment on the regulation of ephedra supplements. After collecting and analyzing those comments, in December 2003, Sec. Thompson announced that the agency had decided to move forward on banning the sale of all dietary supplements containing ephedra, making it the first supplement ever to be banned by the federal government.

### **Ruling Offers Exemption for "Traditional Asian Medicine"**

In issuing its ruling, the FDA concluded that supplements containing ephedrine alkaloids "present an unreasonable risk of illness or injury under the conditions of use recommended or suggested" on the labeling of such products. This conclusion was based, the FDA said, due to studies on the pharmacology of ephedrine alkaloids, scientific literature on their effects, and several adverse events purported to have occurred following consumption of ephedra or ephedrine-containing supplements.

According to Section III B of the final rule, the ban applies only to "dietary supplements containing ephedrine alkaloids, including, but not limited to, those from the botanical species *ephedra sinica* Stapf, *ephedra equisetina* Bunge, *ephedra intermedia* var. *tibetica* Stapf, *ephedra distachya* L., *sida cordifolia* L.

and *pinellia terneta* (Thunb.) Makino or their extracts." However, "conventional food products" that contain ephedrine alkaloids are exempted, as are "OTC (over-the-counter) or prescription drugs that contain ephedrine alkaloids."

Section III B also includes a caveat for the use of ephedra as it applies to "traditional Asian medicine":

Several ephedra species (including those known as *ma huang*) have a long history of use in traditional Asian medicine. These products are beyond the scope of this rule because they are not marked as dietary supplements. The use of ephedrine alkaloids in traditional Asian medicine is discussed in more detail in section V B 5 of this document. As we describe there, this rule does not change how these products are regulated under the act.

Section V B 5 of the ruling deals with the specific use of ephedra as a component of traditional Asian medicine. The FDA received several comments from licensed acupuncturists, herbalists and doctors of Oriental medicine regarding ephedra's safety, preparation, use and long safety record. In response, the FDA stated:

This final rule does not affect the use of ephedra preparations in traditional Asian medicine, although we considered the comments' views and information on the use of ephedra in traditional Asian medicine in the context of their possible relevance to the risks of dietary supplements containing ephedrine alkaloids. This rule applies only to products regulated as dietary supplements.

### **Profession Comments on Ruling**

In the wake of the FDA's ruling, *Acupuncture Today* contacted several of the nation's leading acupuncture, Oriental medicine and herbal product organizations to comment on the decision and what, if any, effect it may have on the profession. The organizations' responses are printed below for review.

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### **Acupuncture and Oriental Medicine Alliance**

The new rule on ephedra (*ma huang*) was published by the FDA in February. By exempting Chinese medicinal herbs from the ban, the FDA has recognized the safety of these products when used by acupuncturists trained to use ephedra correctly. Comments were filed with the FDA by the Acupuncture and Oriental Medicine Alliance, the American Herbal Products Association, and other acupuncture

organizations, pointing out the lack of adverse events associated with trained Chinese medicinal practitioners and explaining that traditional use of this herb is for certain conditions, in small quantities, usually for short periods of time. The exemption from the ban is especially important as the rule included pinellia (*ban xia*), which would have limited our choices for certain treatments.

Recognition of the safe practice of trained herb practitioners is very good news for acupuncturists; however, a lot of work remains to be done to clarify the role of herbs in health care. It has never been more important to join your state and national acupuncture organizations. If you haven't done it yet, meet with your legislators. Let them know that acupuncturists provide important health care in our communities, and that our access to herbs must be preserved.

*Mercy Yule, LAc*  
*Chair, Herb Committee*

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### **Acupuncture and Oriental Medicine National Coalition**

The FDA rule does not exempt ephedrine alkaloids at all - even as used in the practice of herbal medicine. Federal law preempts state law.

The FDA does not regulate the licensure of practitioners, yet the FDA rule will negatively affect all practitioners utilizing materia medica. The FDA rule bars the use of all botanical sources of ephedrine alkaloids determined by the FDA to be a dietary food supplement which is unsafe.

*Richard A. Freiberg, OMD, NMD*  
*Founder/Director*

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### **American Association of Oriental Medicine**

As many of you know, the AAOM's Executive Committee has been working with Health and Human Services Secretary Tommy Thompson's office for the past year, and one of the main issues has been seeking an exemption for Chinese herbs from FDA rules that would either limit or prohibit their availability. Our letters were "hand delivered" to the secretary, and the secretary "directly" forwarded our requests to the FDA. As you also know, the FDA works for Secretary Thompson. Nevertheless, the wheels of government and its agencies grind on in their own ways, and the FDA is certainly not an exception. And so, the FDA

came out with an "alert" announcement on ephedra dietary substances. It is unusual for the FDA to "delay" the issuance of a rule like this, and the FDA did not announce the reasons for the delay. In the first week of February, the FDA finally issued the actual rule.

You may ask, "Have the efforts of the AAOM had any effect on the ephedra ban?" The answer is **yes**. This ban, for now, is only on "dietary supplements." We don't think that was the original breadth of the impact of what the FDA was seeking. It **has** changed, and the AAOM should get some of the credit for the work we have done to intercede on the behalf of practitioners.

The FDA has released the text of the ephedra regulations. The final rule declares dietary supplements containing ephedrine alkaloids adulterated. Regarding herbal formulas used in Chinese medicine, the rule has this to say: "The scope of the rule does not pertain to traditional Chinese herbal remedies."

"This final rule does not affect the use of ephedra preparations in traditional Asian medicine, although we considered the comments, views and information on the use of ephedra in traditional Asian medicine in the context of their possible relevance to the risks of dietary supplements containing ephedrine alkaloids. This rule applies only to products regulated as dietary supplements ... traditional Asian medicine practitioners do not typically use products marketed as dietary supplements."

The FDA bases this conclusion on a position taken in an earlier proposed regulation that said: "Use of botanical sources of ephedrine alkaloids in traditional herbal therapies is beyond the scope of this proposal. Although several ephedra species (including those considered as *ma huang*) have been reported to have a long history of use in traditional Asian medicine ... products bearing claims evidencing that they are intended for therapeutic use are regulated as drugs under the Act."

We believe the direct contact the AAOM has with the Office of the Secretary for Health and Human Services proved instrumental in the FDA allowing this exception. The Office of the Secretary from HHS contacted me on January 2. In our discussion, the AAOM's contact confirmed that the new 'alert' on ephedra would apply to "dietary products for weight loss and energy enhancement," and that this would be reflected in the FDA rule. The office of the Secretary put the AAOM in contact with an individual at the FDA with whom we discussed the FDA rule and specific wording to exempt all Chinese herbs that contain ephedrine alkaloids. It is important to understand that the FDA refrains from specifically mentioning any type of practitioner in these kinds of rules. Although they may address specific substances, they leave scopes of practice to the individual states, so they would avoid giving a specific exemption to Oriental

medicine practitioners.

Although it is great news that the ephedra ban does not apply to Chinese herbal medicine, you can be sure that there are more challenges to come. Because of the importance of this issue, you can be sure we will keep you updated on any new developments.

*Gene Bruno, LAc, OMD*

*President*

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### **Council of Colleges of Acupuncture and Oriental Medicine**

The FDA's recent final rule banning the use of ephedra does not affect the use of ephedra (*ma huang*) preparations used in traditional Asian medicine. The FDA has determined that the ban applies only to products regulated as dietary supplements and that practitioners of traditional Asian medicine do not typically use products marketed as dietary supplements. The agency's final rule does not explicitly address the legal effect of its determination upon state laws that may ban the use of ephedra without a similar exemption for traditional Asian medicine.

The Council of Colleges of Acupuncture and Oriental Medicine believes that any ban on ephedra should contain an exemption for AOM providers. Colleges and programs that have achieved candidacy or accreditation status with ACAOM are subject to standards of education and training that provide support for the safe and effective use of ephedra by AOM providers. Ephedra is one of the most important herbs in the Chinese *materia medica*, with documented use for asthma, colds, and flu in China for some 2,000 years. It is important that the public be educated to learn the distinction between the use of ephedra for new and unproven purposes and for uses that are safe, effective and appropriate when employed by a qualified AOM provider. The Council will continue to assist in this public educational effort while concurrently promoting excellence in AOM education and training.

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### **National Certification Commission for Acupuncture and Oriental Medicine**

The NCCAOM supports the FDA's consumer alert regarding over-the-counter supplements that have ephedra/*ma huang*, but only to the extent that they are available and purchased without consultation with a certified Oriental medicine or Chinese herbology practitioner. Licensed practitioners who are certified in

Oriental medicine or in Chinese herbology have the necessary training to use and prescribe ma huang, and no danger to the public exists when taken under the direction of such qualified practitioners.

*Debra Persinger, PhD*

*Executive Director of Operations*

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### **American Herbal Products Association**

The APHA did not submit a comment to *Acupuncture Today*. However, on Dec. 31, 2003, a day after the initial ephedra ruling was announced, it issued the following statement:

In announcing its decision yesterday morning to ban dietary supplements containing ephedrine alkaloids, the Food and Drug Administration (FDA) acknowledged its authority under the current law to remove products it determines to be unsafe. This is an important message to industry and to consumers who may have been misinformed or confused on this issue.

Over the past decade, there has been an ongoing disagreement between experts, some of whom have concluded that ephedra is appropriate for use by well-informed adults and others who believe that the herb should be banned. FDA has the responsibility and the authority to serve as the arbiter in this controversy, and has now made its decision. The agency has not yet provided any communication as to how it has arrived at its conclusion, but AHPA will evaluate this information as soon as it is available for review.

Importantly, at three separate times during yesterday's press conference, Secretary Thompson mentioned that he believes FDA should have the authority to access adverse event reports associated with dietary supplements. This position is not inconsistent with AHPA's Citizen Petition, submitted to FDA on March 20, 2003, in which it was requested that FDA establish a requirement for dietary supplement companies to submit serious adverse event reports to FDA. AHPA will continue to work toward the development of such a system.

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### **More Scrutiny of Supplements Expected**

While ephedra is the first supplement to be banned by the FDA, evidence suggests the agency intends to look at a number of substances, some of which play a crucial role in the practice of traditional Chinese medicine. In a speech delivered at the University of Mississippi on Jan. 20, FDA Commissioner Mark

McClellan singled out bitter orange, aristolochic acid and usnic acid as ingredients that could come under increased scrutiny. All three have been used in weight-loss supplements; bitter orange has been promoted by some manufacturers as a substitute for ephedra.

"While most supplements are probably safe in the dose people take them, we are concerned about a number of other dietary supplements that are currently on the market," McClellan said. "We will be doing more work in the coming months to more closely evaluate the potential safety risk of these products, and we could take further action to remove unsafe dietary supplements from the market."

### *Resources*

1. Duenwald M. Despite FDA ban, ephedra won't go away. *New York Times* Feb. 17, 2004.
2. Mihoces G. How will sports leagues react to ephedra ban? *USA Today* Dec. 31, 2003.
3. Richwine L. U.S. probing dietary supplements besides ephedra. Reuters Jan. 21, 2004.
4. FDA issues regulation prohibiting sale of dietary supplements containing ephedrine alkaloids and reiterates its advice that consumers stop using these products. Food and Drug Administration press release, Feb. 6, 2004.
5. *Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk*. Food and Drug Administration 21 CFR Part 119, Docket no. 1995N-0304. Published in the Federal Register Feb. 11, 2004.
6. Statement of the American Herbal Products Association on FDA's announcement of a ban on ephedra. American Herbal Products press release, Dec. 31, 2003.



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