

Title 25. Health Services

Part 1. Department of State Health Services

Chapter 229. Food and Drug

Subchapter Y. Regulations to Prohibit the **[Set Standards for the Formulation,]** Sale and Distribution of Dietary Supplements Containing Ephedrine **[from Natural Ephedra]** Alkaloids and to Restrict the Sale and Distribution of Certain Drug Products Containing Ephedrine.

Repeals §§229.462 - 229.463

Amendments §§229.461 and 229.464

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes the amendment of §§229.461 and 229.464 and the repeal of §§229.462 and 229.463, regulations addressing dietary supplements with ephedrine alkaloids and the rule restricting the sale and distribution of drugs containing ephedrine.

BACKGROUND AND PURPOSE

The first three of the four rules which currently comprise Subchapter Y of the food and drug rules (§§229.461 through 229.463), restrict and regulate the sale and distribution of dietary supplements containing ephedrine alkaloids. The fourth rule, §229.464, restricts and regulates the sale and distribution of drugs containing ephedrine. Since adoption of these rules, the U.S. Food and Drug Administration (FDA) has effectively banned entirely the sale and distribution of all dietary supplements containing ephedrine alkaloids by its adoption of 21 Code of Federal Regulations (CFR) §119.1. As the FDA has declared all dietary supplements containing ephedrine alkaloids adulterated foods under section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act, the department's rules regarding dietary supplements containing ephedrine require revision to be consistent with the federal regulations in this area.

Government Code, §2001.039, requires that each state agency review and consider for readoption each rule adopted by that agency pursuant to Government Code, Chapter 2001 (Administrative Procedure Act). Sections 229.461 - 229.464 have been reviewed and the department has determined that the first dietary supplement rule should be amended and the second and third rules repealed to reflect and be consistent with the federal prohibition on the sale and distribution of dietary supplements containing ephedrine alkaloids. The reasons for adoption of the fourth rule, which applies to ephedrine in drugs, continue to exist, and therefore, this rule continues to be needed.

SECTION-BY-SECTION SUMMARY

Amendments to Title 25, TAC Chapter 229 Subchapter Y include adding the words "Prohibit the" and deleting the words "Set Standards for the Formulation" and "from Natural Ephedra" in the subchapter title so that it reads as follows: "Regulations to Prohibit the Sale and Distribution of Dietary Supplements Containing Ephedrine Alkaloids and to Restrict the Sale and Distribution of Certain Drug Products Containing Ephedrine."

Section 229.461 is being amended by changing the title of this rule to "Regulations to Prohibit the Sale and Distribution of Dietary Supplements Containing Ephedrine Alkaloids" and deleting all language of the rule beginning with the word "unless" so that it reads: "The sale or distribution of any dietary supplement containing ephedrine alkaloids is prohibited."

Sections 229.462 and 229.463 are being repealed in their entirety to be consistent with the ban on the sale and marketing of these food products under 21 CFR §119.1

The amendments to §229.464 consist of renumbering this rule as §229.462 and adding the legal citation to the Federal Food, Drug, and Cosmetic Act at the end of this rule, 21 U.S.C. §301 *et seq.*, for reference purposes.

#### FISCAL NOTE

Susan E. Tennyson, Section Director, Environmental and Consumer Safety Section, has determined that for each year of the first five-year period that the sections will be in effect, there will be no fiscal implications to the state or local governments as a result of enforcing and administering the sections as proposed.

#### SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Tennyson has also determined that there will be no adverse effect on small businesses or micro-businesses required to comply with the sections as proposed. This was determined by interpretation of the rules that small businesses and micro-businesses will not be required to alter their business practices in order to comply with the sections.

#### ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

#### STATEMENT OF NO ADVERSE ECONOMIC IMPACT

Pursuant to the requirement of Government Code, §2006.002(c) (amended by House Bill 3430, 80<sup>th</sup> Legislative Session, 2007), the department has determined that none of the proposed changes "may have an adverse economic effect on small businesses subject to the proposed rule." This determination is made because there will be no adverse economic impact on any regulated entity as a result of these amendments.

#### PUBLIC BENEFIT

In addition, Ms. Tennyson has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of enforcing and administering the sections will be by eliminating

unnecessary sections of the rules and making state regulations consistent with federal regulations.

#### REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or public health and safety of a state or sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

#### TAKINGS IMPACT ASSESSMENT

The department has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

#### PUBLIC COMMENT

Comments on the proposal may be submitted to Claire Perkins, Foods Group, Policy, Standards, and Quality Assurance Unit, Department of State Health Services, P.O. Box 149347, MC 2835, Austin, Texas 78714-9347, (512) 834-6770 ext 2173, or by email to [claire.perkins@dshs.state.tx.us](mailto:claire.perkins@dshs.state.tx.us). Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

#### LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

#### STATUTORY AUTHORITY

The proposed repeals and amendments are authorized by Health and Safety Code §431.241, Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of the Health and Safety Code, Chapter 1001. Review of the rules implements Government Code, §2001.039, the four year agency review requirement.

The proposed repeals and amendments affect the Health and Safety Code, Chapters 431, and 1001; and Government Code, Chapter 531.

Sections for Repeal.

§229.462. Products Labels for Dietary Supplements Containing Ephedrine.

§229.463. Advertising and Promotional Literature for Dietary Supplements Containing Ephedrine.