

2/4/2022 email to grower/processors who use additives in products that have not been approved by the US FDA

The Department has reviewed your submission, and your product approval request is **DENIED**.*

Prior approval for the product(s), if issued, is hereby **RESCINDED**.

The Department has reviewed every additive contained in the attached list of products and has determined that additive(s) contained in your product(s) have not been approved for inhalation by the United States Food and Drug Administration. Accordingly, you may no longer produce the product(s). By this notice, the Department advises that products on the attached list meet the conditions for recall under 28 Pa. Code § 1151.42(c)(1). **Accordingly, you MUST follow the mandatory recall procedures outlined in 28 Pa. Code § 1151.42(c)**. Failure to comply will result in the Department acting to impose sanctions against you under 28 Pa. Code § 1141.47.

The Department provides the following rationale for this determination:

In passing the Medical Marijuana Act, the General Assembly specifically declared:

(2) *The Commonwealth is committed to **patient safety**. Carefully regulating the program which allows access to medical marijuana will enhance **patient safety** while research into its effectiveness continues.*

(3) It is the intent of the General Assembly to:

(i) *Provide a program of access to medical marijuana which balances the need of patients to have access to the latest treatments with the need to promote **patient safety**.*

(ii) *Provide a **safe** and effective method of delivery of medical marijuana to patients.*

35 P.S. § 10231.102 (emphasis added).

Further, the Medical Marijuana Act, when recently amended under Act 44 of 2021, explicitly states:

Excipients must be pharmaceutical grade, unless otherwise approved by the department. In determining whether to approve an added substance, the department shall consider the following:

(i) Whether the added substance is permitted by the United States Food and Drug Administration for use in food or is Generally Recognized as Safe (GRAS) under Federal guidelines.

(ii) Whether the added substance constitutes a known hazard such as diacetyl, CAS number 431-03-8, and pentanedione, CAS number 600-14-6.

35 P.S. § 10231.702(a)(5).

You may appeal this action to the Secretary of Health in writing **within 30 days of the date of emailing** of this Notice in accordance with 28 Pa. Code Chapter 1230 (relating to practice and procedure – temporary regulations).

* Please refer to the attachment for a complete list of products that are expressly denied by this notice.

PA Department of Health | Office of Medical Marijuana