

[Concerns Regarding the Coating Produced by Apeel; FDA & the EPA.](http://www.newsreleasewire.com/311549)

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There is a nation wide concern regarding the application of Apeel Science's fruit and vegetable food coatings Edipeel and Organipeel.

Most of the 'misinformation' as referenced by Apeel, seems to be concentrated on their utilization of various metals/heavy metals such as lead, arsenic, palladium, heptane, and mercury during their chemical processing.

Apeel filed with the FDA, the GRAS Notice (GRN) No.00886 Application, entitled; 'Generally Recognized as Safe (GRAS) Notice for a Mixture of Monoacylglycerides Derived from Grape Seed.' [1]

In reviewing this application and subsequent correspondence from the FDA, the NTEF has questions that we feel necessitate a response. A letter was sent to Dr. Jenny Du, Ph.D., Senior Vice-President Operations for Apeel Sciences. [2]

The NTEF IS questioning Apeel's FDA Application as they provided correspondence to the FDA that their Application: '*Apeel informs the FDA that at the time of submitting GRN 000 886, the process described in the notice to make MDAG was in a proof -of-concept stage of development, had not been commercialized, and that Apeel has no plans to commercialize the MDAG that were the subject of GRN 000 886.*' [6]

So just what are they using and processing with, as they seem to have completely altered their production.

Apeel states: '*...eradicate food insecurity for the most vulnerable people while sustaining our health ...*.' '*Apeel's products are non-GMO... do not contain regulated allergens like milk, egg, fish, molluscan shellfish, tree nuts...*'

Vulnerable? They specifically referenced 'regulated allergens', it is obvious that other 'non-regulated' allergies aren't on their radar or something that they aren't concerned about. Aren't they aware that consumers can have grape et al allergies and cross reactivity with other consumables? IgG and IgE mediated immune responses should be a factor in Apeel's policy to require labeling upon all coated fruits and vegetables?

*Conventional produce coating is Edipeel, is made of plant-based mono- and diglycerides. Organipeel is made of citric acid, baking soda and plant-based mono-and diglycerides... has been discontinued to make way for next-generation*

*formulations...'* What plants are used? In their application they referenced grape seed, why isn't this disclosed/incorporated on their website? Where is the citric acid sourced? Mold? What if anything will be substituted or added to Organipeel? Will they be filing another EPA Application under FIFRA?

EPA LABEL: June 7, 2019, Registration No. 92708-1 is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act. [3]

ACTIVE INGREDIENT: Citric Acid	0.66% BY WT
OTHER INGREDIENTS:	99.34% BY WT

Is the Citric Acid derived from cultures of the mold *Aspergillus niger*? Those with mold allergies need to be notified to avoid Organipeel. Is it citric fruit derived? We have concerns regarding those with citric allergies.

In FDA correspondence there has been references to the following regulations regarding potential violations: 21 CFR 184.1505, 21 CFR170.35, Section 301(II) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), section 505 of the FD&C Act.

*Section 301(II) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) Section 301(II) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(II)(1)-(4) applies.[4] In our evaluation of Apeel Sciences' notice concluding that MDAG is GRAS under its intended conditions of use, we did not consider whether section 301(II) or any of its exemptions apply to foods containing MDAG. Accordingly, our response should not be construed to be a statement that foods containing MDAG, if introduced or delivered for introduction into interstate commerce, would not violate section 301(II)*

*This letter is not an affirmation that MDAG is GRAS under 21 CFR170.35. Unless noted above, our review did not address other provisions of the FD&C Act. Food ingredient manufacturers and food producers are responsible for ensuring that marketed products are safe and compliant with all applicable legal and regulatory requirements.'* [5]

*FDA letter of April 12, 2024, Apeel informs the FDA that at the time of submitting GRN 000 886, the process described in the notice to make MDAG was in a proof -of-concept stage of development, had not been commercialized, and that Apeel has no plans to commercialize the MDAG that were the subject of GRN 000 886. Further, Apeel indicates that the MDAG that Apeel is using are manufactured via the process described in 21 CFR 184.1505.*

*Section 301(II) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)  
[5] In issuing this additional correspondence, we did not consider whether section 301(II) or any of its exemptions apply to foods containing MDAG. Accordingly, our additional correspondence should not be construed to be a statement that foods containing MDAG, if introduced or delivered for introduction into interstate commerce, would not violate section 301(II).’ [6]*

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[1] Apeel’s FDA GRAS Original Petition

[2] NTEF’s letter to Dr. Jenny Du, Ph.D.

[3] EPA Label for Organipeel listed as a pesticide.

[4] FDA Response Letter GRAS Notice No. GRN 000648 to Apeel’s attorney Mark L. Itzkoff. dated December 13, 2016

[5] September 11, 2020, FDA Revised Letter referencing GRN 000886, July 13, 2020.

[6] FDA Follow-up letter dated May 24, 2024, regarding supplemental submission received April 12, 2024.]