



Analysis of FDA Warning Letters for Social Media Prescription Drug Promotion

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Background/Purpose:

The FDA Office of Prescription Drug Promotion published 4 draft guidance's regarding the use of social media in drug promotion. The purpose of this study was to analyze warning letters issued by the FDA for violations of advertising and promotional regulations to determine how the number and nature of these violations changed over time.

Methods:

The FDA database for warning letters was extracted on September 21, 2022, with letters dating from January 1, 2017. Letters pertaining to unapproved drug products, herbal supplements, tobacco products, manufacturing procedures, and drug adulterations were removed from the dataset. Separate search queries were performed on the data using the following terms: "Facebook", "YouTube", "Twitter", "LinkedIn", and "Instagram". The content of these letters was analyzed to evaluate the method in which the FDA learned of these violations, the violations cited, and the social media platform used.

Results:

A total of 3252 warning letters were issued by the FDA between January 1, 2017 and September 21, 2022. Upon search query completion only 5 letters remained related to the misbranding of an FDA approved prescription drug product on a social media site. A content analysis showed that pharmaceutical companies who received warning letters often failed to balance the risks of their therapies in relation to the benefits presented and deviated from the approved indications of their drugs in their advertisements. The most common advertising medium utilized was Google Ads, Facebook, and YouTube. The FDA became aware of violative content primarily through the Bad Ad Program or directly through manufacturer social media pages.

Analysis of FDA Social Media Promotional Violations Between January 2017 and September 2022

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Our analysis suggests that the most common violation was false or misleading risk presentation - manifested in the form of failure to balance risks and benefit information

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Conclusion:

The limited number of relevant warning letters issued to pharmaceutical companies suggests that the industry is appropriately utilizing social media. None of the warning letters involving approved FDA products were relevant to platforms such as Instagram, Twitter, or LinkedIn. This suggests that either pharmaceutical companies are properly utilizing these websites, or that barriers exist which may be deterring pharmaceutical companies from tapping the full potential of these sites as an advertising platform.