Abstract

Objective: To evaluate the number and type of warning letters issued by the US Food and Drug Administration (FDA) to pharmaceutical manufacturers for promotional violations. Methods: Two reviewers downloaded, printed and independently evaluated warning letters issued by the FDA to pharmaceutical manufacturers from years 2003-2008. Misleading claims were broadly classified as clinical, Quality-of-Life (QoL), and economic claims. Clinical claims included claims regarding unsubstantiated efficacy, safety and tolerability, superiority, broadening of indication and/or omission of risk information. QoL claims included unsubstantiated quality of life and/or health-related quality of life claims. Economic claims included any form of claim made on behalf of the pharmaceutical companies related to cost superiority of or cost savings from the drug compared to other drugs in the market. Results: In the 6-year study period, 65 warning letters were issued by FDA, which contained 144 clinical, three QoL, and one economic claim. On an average, 11 warning letters were issued per year. Omission of risk information was the most frequently violated claim (30.6%) followed by unsubstantiated efficacy claims (18.6%). Warning letters were primarily directed to manufacturers of cardiovascular (14.6%), anti-microbial (14.6%), and CNS (12.5%) drugs. Majority of the claims referenced in warning letters contained promotional materials directed to physicians (57%). Conclusion: The study found that misleading clinical outcome claims formed the majority of the promotional violations, and majority of the claims were directed to physicians. Since inadequate promotion of medications may lead to irrational prescribing, the study emphasizes the importance of disseminating reliable, credible, and scientific information to patients, and more importantly, physicians to protect public health.

Keywords

Advertising as Topic, Marketing, Drug Industry, United States Food and Drug Administration, United States.