Key Points of FDA Health Care Professional Outreach
(Bad Ad Program)

What is the Bad Ad Program?

The Bad Ad Program is an FDA-sponsored outreach program designed to educate health care professionals about the role they can play in helping FDA ensure that prescription drug advertising and promotion is truthful and not misleading.

The program helps health care professionals who prescribe medications or otherwise make selection decisions about the use of prescription drugs for patients (including physicians, nurse practitioners, physician assistants, and pharmacists) to better understand what constitutes appropriate prescription drug promotion and advertising and how to report possible violations.

What are the goals of the program?

The program seeks to increase the effectiveness of DDMAC's surveillance program, especially with regard to curtailing inappropriate promotional activities of sales representatives visiting the offices of health care professionals and delivering presentations to health care professionals during industry-sponsored dinner and speaker presentations.

Why educate health care professionals?

DDMAC's traditional surveillance activities have been somewhat limited by its inability to monitor drug promotion in settings such as physician offices, local dinner programs, and promotional speaker training sessions. By raising awareness about misleading promotion and providing an easy process for reporting it, FDA can gain the valuable assistance of health care professionals in helping to decrease the number of misleading promotional messages about prescription drugs.

Is the program only for health care professionals?

Anyone can submit a complaint to FDA. The Bad Ad Program is focused primarily on health care professionals. FDA also has an educational campaign designed to educate consumers about misleading direct-to-consumer (DTC) promotion. The program is called EthicAd and is web based. It can be accessed by the following internet link: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/default.htm

FDA notes that according to a recent Congressional Budget Office Brief[1], promotional spending on sales promotion to health care professionals outpaces DTC spending by almost 3 to 1. Therefore, the Bad Ad Program provides a valuable opportunity for FDA to increase its surveillance efforts in the largest area of prescription drug promotion.

How does the program work?

To kick off the Bad Ad Program, DDMAC will be exhibiting at some of the major medical conferences starting in May of 2010. At these conferences, DDMAC reviewers will be speaking with prescribers regarding how to recognize misleading prescription drug promotion and how to report any potential violations to FDA. Please look for FDA's booth where you can learn more about recognizing and reporting misleading drug promotion.

What does FDA intend to achieve with the Bad Ad Program?

The main purpose of the Bad Ad Program is to raise awareness among health care professionals about the importance of helping FDA in its efforts to prevent misleading promotion of prescription drugs. By providing information to health care professionals about how to identify and report misleading promotion, DDMAC will be able to decrease the number of misleading promotional messages directed to health care professionals.

How can health care professionals report a potential violation?

To report a potential violation, health care professionals can send an e-mail to badad@fda.gov or call 877-RX-DDMAC.

Can reports of potential violations be submitted anonymously?

Reports can be submitted anonymously by health care professionals. However, FDA encourages professionals to include contact information so that DDMAC officials can follow-up if necessary for more information.

What will happen after a health care professional reports a potentially inappropriate promotion to DDMAC?

Once a report is filed, DDMAC will evaluate the report to determine if it meets the criteria needed to take a regulatory action. If DDMAC finds the promotion to be in violation, DDMAC will move forward with a risk-based enforcement strategy, which may include an Untitled Letter, Warning Letter, or referral for criminal investigation. If the report does not meet the required criteria at the time, it will serve as valuable information in focusing our ongoing surveillance activities. Although DDMAC will not

[1] http://www.cbo.gov/ftpdocs/105xx/doc10522/12-02-DrugPromo_Brief.pdf

be able to follow up with each individual who files a report, health care professionals can view regulatory actions taken as a result of reports on FDA's Warning Letter page [http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm197224.htm].