Oh Oh Telephone Line: FDA Issues an Untitled Letter for an Unlawful Professional Telephone Script

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While the Food and Drug Administration's Office of Prescription Drug Promotion (OPDP) issues a number of enforcement letters for unlawful activity, every so often, we find certain letters of particular interest because of the nature of the promotional item. Recently, OPDP channeled the 1970s British rock band, Electric Light Orchestra, when it issued an Untitled Letter to a drug company for a professional telephone script that omitted important risk information and material facts (think, "Oh Oh Telephone Line - Give Me Some Time").[1] Here, we summarize OPDP's concerns and offer observations, based on our experience in participating in a number of clients' Promotional Review Committees and advising on promotional materials, including telephone scripts.

Background and FDA Objections

- The company submitted a professional telephone script, which it used to promote its prescription drug product.
- The script made efficacy claims about the product, but did not include important risk information, such as the contraindication, all of the warnings and precautions, and common side effects.
- The script included a statement, "I can email the full prescribing information for [product name] or you can also access it at the [product name] website [URL address]. Which do you prefer?" However, FDA said that this was insufficient, because it omitted the risk information.
- The script included the product name and a general description of the approved indication. However, the full indication was not provided and material facts that limited the indication were omitted. The script also failed to include important material information about dosing at the initial use of the product.
- The script did not include the established name in direct conjunction with the product's proprietary name, as required by regulation.

AGG Observations

1. As noted, frequently, OPDP issues an enforcement letter to highlight a particular type of promotional activity that companies might think are under the regulatory radar. Here, OPDP reminds industry that telephone scripts with product names are labeling and, therefore, must comply with applicable requirements.
2. We review a number of telephone scripts. We hear, often, that the company only has a few moments with the doctor and including important safety information will divert the doctor's attention and make the script too long. The bottom line is that FDA is less concerned about "the need for speed" or those "precious moments." Compliance is compliance and, if a company wants to provide the good - - indication and efficacy claims - - it must provide the balanced bad - - risk information.

1 The Untitled Letter is available at www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyfda/warninglettersandnoticeofviolationletterstopharmaceuticalcompanies/ucm405441.pdf.

3. Related to the point above, it is inadequate to provide the positive information in one setting and direct the recipient to another location for the negative. Remember FDA's enforcement letters concerning Google-sponsored links. The good and bad must go together.

4. Due to space or time limitations, companies frequently want to shorten the indication and, in client terms, "summarize" or "simplify" the indication. Don't. The approved indication is sacrosanct; it's what the company and FDA agreed for product approval. We recommend the indication be used verbatim from the approved prescribing information to minimize any potential misunderstanding or confusion. However, if there are modifications made to the indication in any promotional piece, be sure to include any limitations or qualifiers contained in the indication. These are material and, failure to include, is misleading and does not portray an accurate story.

5. While some in the industry might think the failure to include the established name is not so important ("we're trying to promote our brand, not the active ingredient," we hear often), it is. The bottom line is that FDA requires the presentation of the established name in direct conjunction with the proprietary name. Period.

   To paraphrase the Electric Light Orchestra song, give the script more time (and attention).

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