Homeopathic Regulation Has Come to Stay

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FDA closed out 2017 with a brief, but long-awaited, draft guidance on *Drug Products Labeled as Homeopathic* (Homeopathic Guidance), which lays out FDA's new regulatory strategy for these products.[1] Under the Federal Food, Drug, and Cosmetic Act (FDCA), a "drug" is defined to include homeopathic drugs which are products listed in the Homeopathic Pharmacopeia of the United States (HPUS).[2] Homeopathy is an alternative medical practice originating from the 1700s that is based on two main principles:

1. A substance that causes symptoms in a healthy person can be used in a diluted form to treat symptoms and illnesses; and,
2. The more diluted the substance, the more potent it is.

In the Homeopathic Guidance, FDA announced that Compliance Policy Guide (CPG) 400.400, *Conditions Under Which Homeopathic Drugs May be Marketed* has been withdrawn. The CPG was originally issued in 1988 and had been the main source of guidance on FDA's regulation of homeopathic drugs for nearly 30 years. Under the CPG, homeopathic drugs could be marketed if they met the standards for strength, quality, and purity set forth in the HPUS and were properly labeled.[3]

In large part, over the past decades, FDA left homeopathic drugs largely unregulated provided they met the conditions outlined in the CPG. In recent years, however, there has been a significant increase in the number and types of products marketed as homeopathic and their potential impact on public health has increased.

FDA began its reappraisal of homeopathic drugs almost three years ago when it held a public meeting in April 2015 to discuss the use of and regulatory framework for homeopathic drugs. Over 9,300 public comments were submitted to the docket for the meeting.[4] In December 2017, after evaluating the public comments and the information obtained from the public meeting, FDA issued the Homeopathic Guidance and announced the withdrawal of the CPG.

FDA will now apply a risk-based enforcement approach to drug products labeled as homeopathic. FDA identified six main enforcement priorities in the Homeopathic Guidance:

1. Products with reported safety concerns
2. Products that contain or purport to contain ingredients associated with potentially significant safety concerns (e.g., controlled substances, infectious agents, high concentrations of potentially toxic ingredients)
3. Products for routes of administration other than oral and topical
4. Products intended to be used for the prevention or treatment of serious and/or life-threatening diseases and conditions
5. Products for vulnerable populations (e.g., infants and children, elderly, pregnant women)
6. Products deemed adulterated under section 501 of the FDCA (e.g., because the product

1 https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM589373.pdf
2 21 U.S.C. § 321(j)
3 https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074360.htm
4 https://www.regulations.gov/docket?D=FDA-2015-N-0540

was not manufactured in accordance with current good manufacturing processes (CGMPs)).

In the press announcement accompanying the Homeopathic Guidance, FDA highlighted several products for which it has issued warnings in recent years. Many of these products raised issues that are reflected in the enforcement priorities announced in the Homeopathic Guidance, including teething tablets and gels found to contain belladonna, homeopathic asthma products, and products containing strychnine. Teething tablets are intended to be used by infants, a vulnerable population; belladonna and strychnine are both toxic ingredients; and asthma is a serious condition.

FDA is not the only agency to reexamine its approach to homeopathic products. The Federal Trade Commission (FTC) has regulatory authority over advertising and labeling of homeopathic drugs that are sold over-the-counter (OTC). The FTC issued an Enforcement Policy Statement on Marketing Claims for OTC Homeopathic Drugs (Policy Statement) in November 2016, which marked a turn towards increased scrutiny of homeopathic drugs.[5] In its Policy Statement, the FTC explained that because "the case for efficacy is based solely on traditional homeopathic theories and there are no valid studies using current scientific methods showing the product's efficacy" for the vast majority of homeopathic drugs, any claims that homeopathic products have a therapeutic effect lack a reasonable basis and are likely misleading.

FTC required that promotion of OTC homeopathic products for indications that are not substantiated by "competent and reliable scientific evidence" must include a disclaimer in order to not be misleading. The disclaimer must communicate to consumers that there is no scientific evidence that the product works and the product's claims are based only on theories of homeopathy from the 1700s that are not accepted by most modern medical experts.

This is not the first time FDA has used a risk-based enforcement approach for a certain class of drugs. As noted in the Homeopathic Guidance, FDA uses a similar enforcement strategy for other marketed unapproved new drugs.[6]

AGG Observations

1. As a general matter, FDA's actions amount to removing special considerations for homeopathic drugs and putting them on the same footing as other drug products. Because of some of the inherent qualities of homeopathic drugs (e.g., the infinitesimal amount of the "active ingredient"), compliance with certain standards may be challenging for the industry.

2. In September, FDA issued a Warning Letter to a homeopathic drug manufacturer for multiple alleged failures to follow CGMPs.[7] Although the Warning Letter predates the policy announcement, it suggests that CGMPs will be an area of inspection and enforcement focus going forward.

3. Although the FTC announced its new policy more than a year ago, we haven't yet heard of any company receiving any communication from the FTC about its homeopathic products' not complying. We understand that industry and the FTC have been in discussions for the past year about permissible language for the marketing claim statement the Policy Statement requires regarding a lack of substantiation in appropriate cases.

5 https://www.ftc.gov/system/files/documents/public_statements/996984/p114505_otc_homeopathic_drug_enforcement_policy_statement.pdf
6 https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070290.pdf
7 https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm575120.htm

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