



October 26, 2019

JOINT STATEMENT

Statement Regarding the FDA's Notice of Withdrawing Compliance Policy Guide Sec. 400.400 for Homeopathy

The FDA today announced a withdrawal of Compliance Policy Guide Section 400.400 and the issuance of a new Draft Guidance for homeopathy.

The American Institute of Homeopathy, North American Society of Homeopaths, National Center for Homeopathy and Americans for Homeopathy Choice fully support the FDA's efforts to regulate all products that are labeled homeopathic but that are not in fact homeopathic. FDA should ensure that only homeopathic products should bear the label "homeopathic."

We also support the FDA's responsibility to enforce proper manufacturing processes for all drug products including those properly labeled as homeopathic.

Homeopathic drugs are universally recognized as inherently safe and specifically defined as drugs by the Food Drug and Cosmetic Act (FD&CA). It is our strong view that a separate section of the FD&CA that sets out the definition of a "new drug" explicitly excludes homeopathic drugs.

The new drug designation in the law is designed to address inherently dangerous chemicals that are used as drugs, requiring a system of review that demonstrates that the benefits of a chemical must outweigh the risks of a chemical before it can be sold as a drug.

The FDA's new guidance moves in a direction we support but has a few gaps that need to be addressed. In particular, we believe the new guidance should clearly differentiate between those products that are in fact homeopathic and those products improperly labeled as homeopathic, allowing FDA to clearly focus its energies on products falsely labeled as homeopathic.

It's important to stress that this new guidance is in draft form. We look forward to continuing our very productive conversations with the FDA to clarify these matters.

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