Q&A from FDA Consumer Call Webinar

(provided by Eric L. Foxman, RPh, member of AAHP & HPCUS)

Many questions were asked during the FDA Consumer Call Webinar, hosted by NCH on June 9, 2015. The questions below are written answers to those questions. These answers are not official positions of any organization; rather they are valuable insights from one of our distinguished presenters.

**What is the potential outcome in respect of nosodes - Tubercullinum, Medorrhinum, etc?**

There is nothing in the present sequence of events aimed at any particular type of homeopathic drug product. FDA seems to feel comfortable with substances that are monographed in the HPUS. As has been the case for the 25 years of the CPG, companies marketing homeopathic products containing substances that are not monographed in the HPUS are required to have "documentation that the substance is generally recognized as homeopathic."

Beyond that, there is the very real question, and potential concern regarding non-monographed substances: if there is no accepted standard (e.g. an HPUS monograph) that clearly defines the material from which a homeopathic medicine is produced, how can consumers be sure that a product is made properly and from the right starting material? I will note that most nosodes are not monographed in the HPUS. In my consulting experience, I have encountered more than one instance in which different companies are using somewhat varying starting materials but labeling them with the same homeopathic nomenclature. With some substances, including a number of nosodes, this can be an issue because various literature references do not agree with each other in defining the material used historically.

What will come of this situation is not an outcome of the hearing; however, it may be an issue that needs to be addressed as the Agency becomes more aware of the subtleties of homeopathic medicines.

**Would it be possible to get a copy of the question Eric is referencing to help us write a constructive comment to the FDA?**


The eight questions I referred to are identified about 2/3 of the way down at "Scope of the Public Hearing" section.

**Do you want our clients to take the survey and comment?**

Yes, Practitioners' clients should be encouraged to both take the survey and to submit comments. The first is being collected by NCH for a presentation on aggregate consumer attitudes. The second is direct submission of individual comments.

**How can AAHP support pharmacists on the job & improve education?**

The AAHP website provides a wealth of information. If pharmacists wish to contact the AAHP directly (info@aahp.info), they can request a reprint of a CE course with lots of background information (accreditation for CEUs has expired, but the info is still valid).
What is the best outcome from FDA? What is the worst outcome?

In my opinion, the best outcome is an increased awareness by FDA of what is appropriately a homeopathic product and what is not, coupled with an increased focus on enforcement of existing requirements to remove "outliers" and "bad actors" from the market. We all suffer when inappropriate products (through either ignorance or deceit) muddy the homeopathic market. If those can be gotten rid of (a very good outcome), we all will be better off.

A worst outcome would be the total removal of homeopathic products from the market. HOWEVER, FDA does not have the resources, the will, the desire, or the statutory authority to do that. Thus a realistic worst outcome must be somewhere in between. I don’t know what it would be. Surely, with increased awareness will come increased enforcement of existing requirements. Some homeopathic manufacturers will be unprepared to meet those challenges, but that is not a result of the hearing. That will be a result of casual and longer-term neglect on the part of those manufacturers who have not been complying with regulations for years because they mistakenly felt the rules did not apply to them.

When we address homeopathic products that are over the counter, what guidelines do you recommend: single remedies, potentized remedies, or combination remedies?

The primary criterion for “OTC-ness” is the indication (therapeutic purpose) on the labeling. The usual concise definition of an OTC indication is it is self-diagnosable, self-limiting, and does not require trained medical intervention (for either diagnosis or follow-up evaluation). Thus, a patient can know if they have a “cough” (= OTC-ness), but not if they have an “ulcer” (= prescription required). A “cures cancer” indication would NOT be an OTC indication.

Notice that this has nothing to do with whether the product is a single remedy or a combination! The intended use of the product (not the formulation) is the defining criteria for OTC / Rx-only status.

Can you please repeat the name of the mother who put out a video re: homeopathy?

Nancy Peplinski - her FDA presentation notes can be found at: http://www.fda.gov/downloads/Drugs/NewsEvents/UCM443492.pdf

What is the CPG?

The “CPG” is the FDA’s Compliance Policy Guide 400.400. This is an internal Agency document that gives FDA personnel guidance on how to enforce regulations with homeopathic products; it provides some clarity for situations in which homeopathic drug products do not fit well with the existing regulatory structure. It also provides for some circumstances for which other requirements do not apply.

For those who wish to read it, the CPG is available here: http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074360.htm

For those of us who submitted prior to 4/20, is it useful to submit another comment?

A follow-up comment might be helpful, provided it focuses solely on new information; a repetition of what was previously stated is a waste of time and will be ignored. One might want to note that one is submitting an addition to a prior comment (perhaps include the original date), and possibly the reason for the additional submission (make this short - maybe only 1 sentence). If the prior comment was submitted anonymously, there will be no connection between the two; but I, personally, wonder why one would submit anonymously if one is stating a strongly held thought that one stands behind and wants FDA to be aware of.
Are we going to split hairs for example, between Bach flower essences and actual homeopathic remedies?

At this point in time, FDA’s questions and focus seems to be a: do consumers have enough information to make informed decisions; and b: products labeled with serious medical indications that are being promoted for OTC sale. I suggest that comments focus on these two subjects and not on specifics.

I will note that the starting materials used in flower remedies are (almost all) in the HPUS. The manufacturing must comply with the HPUS guidelines for the resulting product to be homeopathic. It would be silly to argue that onions are a primary ingredient in French Onion Soup, and therefore Allium Cepa cannot be a homeopathic medicine. Likewise, it is a sidetrack to spend time (‘split hairs’) about different types of products when the substances are in the HPUS. For FDA’s education at this time, focus on the questions that FDA has raised in its Announcement Notice.

What is the sudden interest of our Government, since we have had regulation guidelines since FDA’s inception?

The CPG has been in effect for 25 years. I would suggest that FDA personnel have recently realized that their awareness of the homeopathic market and homeopathic products has diminished in the last 10 years or so. I think we are seeing an attempt on FDA’s part to fill in their knowledge gaps. From our (AAHP’s) conversations with Agency personnel, I would draw the conclusion that FDA realizes their enforcement posture is out of date with today’s market and they want to know more in order to appropriately enforce regulatory requirements.

Who actually has the money to advertise homeopathic remedies?

At first glance, one might assume that TV, Radio, Newsprint advertising might be too expensive. However, anyone with a website (many available for extremely low cost if not free) just need to invest a few hours to promote their products. That is advertising! If I had a product line, I could advertise it for a couple of hundred dollars and a few days of effort. So, who has the money? Just about anyone who “wants to make a buck.”

How do America's standards compare to the European markets of these "outlier" products?

Europe sells compound homeopathy, right?

Please do not confuse “outlier” products with combination or compound homeopathic remedies. Provided a product is manufactured according to the HPUS, and its’ labeling is compliant with regulatory requirements, it is not an “outlier” product; the HPUS does have manufacturing and labeling guidelines for combination products. By “outliers”, I am referring to a) products labeled as homeopathic but which are not manufactured according to an HPUS monograph or guideline; b) and especially products that are labeled for (have indications for) very serious medical conditions but are being sold OTC.

With that being said, it is more difficult to compare European markets with the US market, because the registration process is different. However, in all regions of the world, there are charlatans who try to take advantage of the marketplace; this is not a phenomenon unique to the US. This is one large source of “outlier” products that the FDA and AAHP are concerned about.