Homeopathic Product Regulation:
Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century

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American Association of Homeopathic Pharmacists

American Association of Homeopathic Pharmacists

- Trade association representing manufacturers of homeopathic drugs
- Founded in 1923
- Members produce 90% of products known to AAHP
  [AAHP estimates retail market at $800M]
- 29 manufacturer members, many date to founding
- First operating principle is to encourage regulatory compliance
- Committed to partnership with FDA in public health mission

Education at AAHP

- *Compliance through Education*
- Webinars, seminars, white papers, and technical articles
- Efforts open to members and non-members
- AAHP amplifies FDA's message of compliance

Origins of the Compliance Policy Guide 400.400

Developed collaboratively by FDA and representatives of AAHP

Collaboratively

Compliance policy guide is effective and efficient

Efficient & Effective

Supports FDA by providing broad enforcement authority to protect the public health

Enables broad enforcement authority

Past Communications with FDA

- FDA point person for homeopathic products issues
- Proactive two-way dialog
- AAHP made FDA aware of potentially misbranded products

Communications with FDA: Recommendations

Establish dedicated resources on homeopathic issues

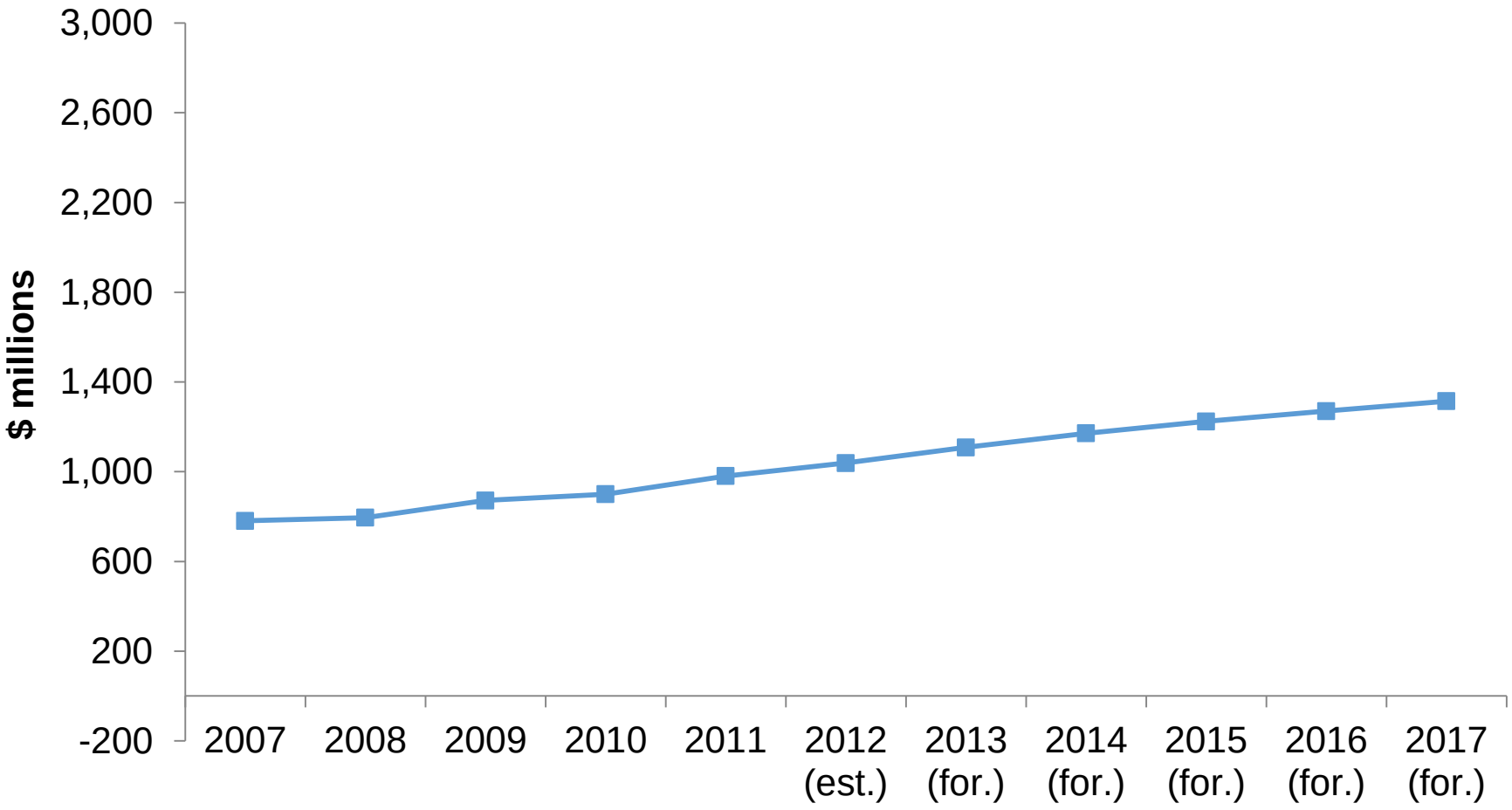
Safety of Homeopathic Medicines

- Exposure ≠ Adverse Event (AE)
- Exposures to homeopathic medicines are <1 % of all reports to AAPCC
- Homeopathic manufacturers are required to report SAEs under MedWatch
- Low numbers of SAEs reported to FDA

U.S. Sales Homeopathic Products

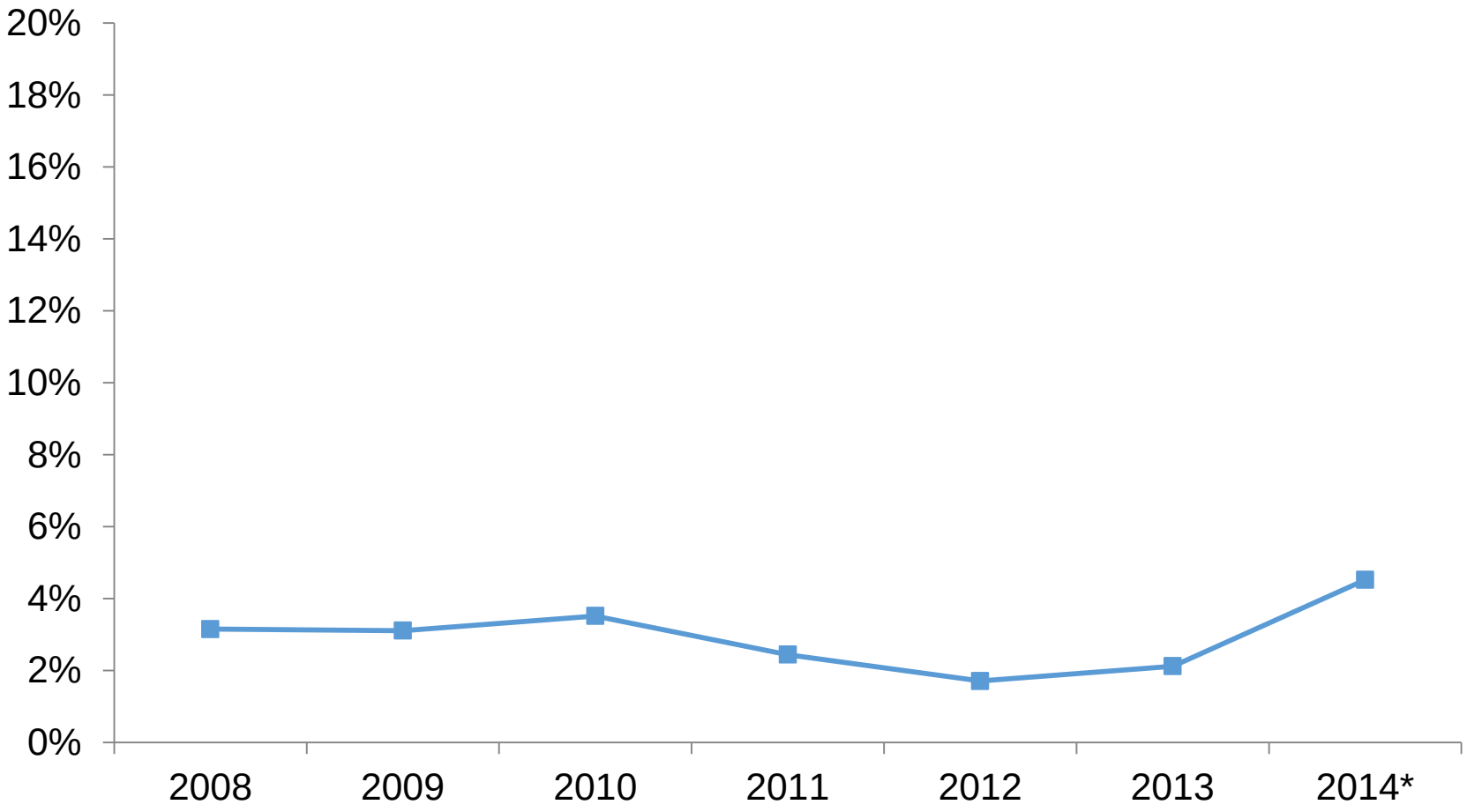
FDA	• Reports 3 billion in sales
Mintel	• Reports 1 billion in sales
Nielsen	• Reports 500 million in sales (Food Drug and Mass outlets)
AAHP	• Reports 800 million – 1 billion in sales
European Mkt	• Reports 2 billion in European sales

Growth Projections for Homeopathic Drugs



Mintel/based on data provided courtesy of Nutrition Business Journal and Penton Media, Inc.

Product Launches for Homeopathic Drugs



*as of June 2014

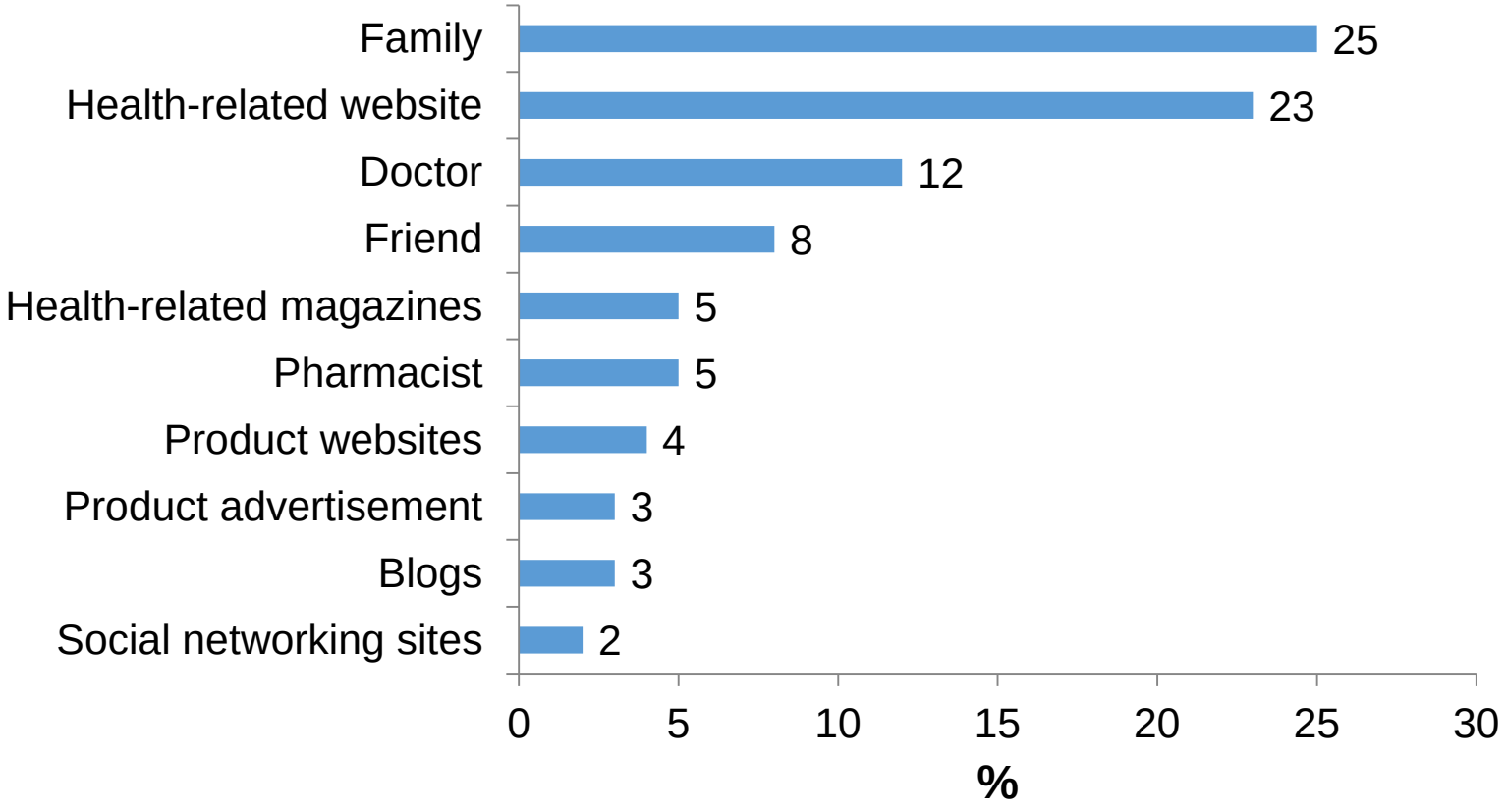
Source: Mintel GNPD

Responding to FDA Questions: Question 1

What are consumer and health care provider attitudes towards human drug and biological products labeled as homeopathic?

- Consumers most likely to buy homeopathic medicines are committed to their health and devote considerable research effort in evaluating health care choices
- Many consumers buy homeopathic medicines based on the advice of health care providers, friends, family members, and internet research

Sources of Information for Homeopathic/Herbal Users



Base: 495 internet users aged 18+ who used herbal/homeopathic remedy

Responding to FDA Questions: Question 1

What are consumer and health care provider attitudes towards human drug and biological products labeled as homeopathic?

- Today as many as 20,000 physicians incorporate homeopathic medicines into their daily practice
- Physicians rely on manufacturers to produce high-quality medicines for treating their patients
- Physicians welcome certain label information such as warnings to inform consumers of signs of disease progression

Responding to FDA Questions: Question 2

What data sources can be identified or shared with FDA so that the Agency can better assess the risks and benefits of drug and biological products labeled as homeopathic?

- *American Association of Homeopathic Pharmacists* *www.aahp.info*
- *Homeopathic Pharmacopoeia Convention of the United States* *www.hpus.com*
- *American Institute for Homeopathy* *www.homeopathyusa.org*

Responding to FDA Questions: Question 3

Are the current enforcement policies under the CPG appropriate to protect and promote public health? Are there alternatives to the current enforcement policies?

- Current regulatory framework is effective
- CPG gives FDA adequate support for misbranding warning letters
- FDA takes swift and comprehensive action with support of CPG

AAHP recommendation: Direct dialog with industry regarding range of OTC indications and maintain existing surveillance and enforcement activities

Responding to FDA Questions: Question 4

Are there areas of the current CPG that could benefit from additional clarity?

- Definition of homeopathic drug could benefit from clarification
- Lack of clarity on range of symptoms, indications, and therapeutic categories amendable to self-diagnosis and self-treatment
- Problem not limited to homeopathic drug products

AAHP recommendation: Engage homeopathic medical and pharmacy experts in this area

Responding to FDA Questions: Question 5

Is there information regarding the regulation of homeopathic products in other countries that could inform FDA's thinking in this area?

- Regulated as drugs in most countries
- EU: market authorization based on quality, safety, and efficacy information from literature
- Premarket authorization processes are overwhelming
- Backlogs > 3 years common
- HPCUS is expert organization

Responding to FDA Questions: Question 6

What would be an appropriate regulatory process for evaluating homeopathic indications for OTC use?

- Vast majority of homeopathic OTC drug products appropriately labeled in compliance with HPUS and the FDA regulations as published in the Code of Federal Regulations
- Branded products at retail generally fall into OTC monograph categories established by FDA as amenable to self-diagnosis and self-treatment by lay persons
- AAHP supports FDA regarding responsible labeling of OTC products

Responding to FDA Questions: Question 6

What would be an appropriate regulatory process for evaluating homeopathic indications for OTC use?

- AAHP supports enforcement action by FDA directed against misbranded products

AAHP recommends: FDA engage homeopathic medical and pharmacy experts in the evaluation of OTC indications treatable by homeopathic products.

Eric L. Foxman, R.Ph.

Secretary, American Association of Homeopathic Pharmacists

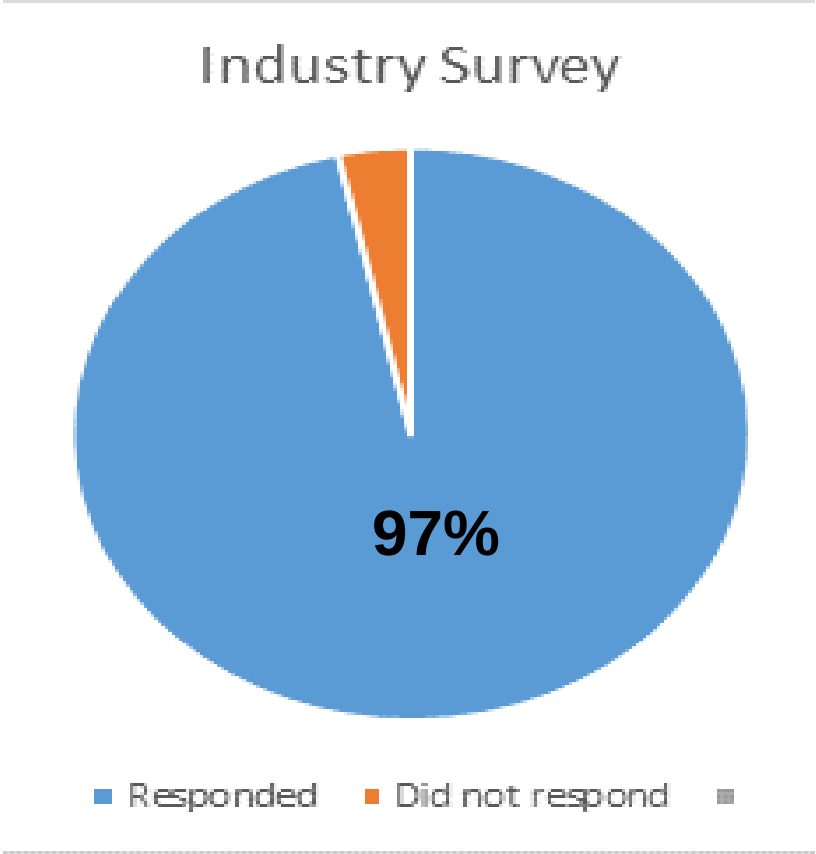
Responding to FDA Questions: Question 7

What processes do companies currently use to evaluate whether such products, including their indications for use, are appropriate for marketing as an OTC drug?

- AAHP member firms undertake a deliberate and conscientious approach when developing OTC indications
- Majority of members look to FDA's tentative and final monographs for OTC drugs when establishing indications for use

Survey of Member Companies

- Fielded
  March 30, 2015 –
  April 7, 2015
- 28 companies responded = 97% of members
- 90% of the OTC homeopathic market



Survey of Member Companies

Survey Question: Do you label and/or market any OTC homeopathic drug products? (Yes or No)

26 of 28 responded YES

2 N/A: no products under their own labeling

Based on 28 respondents

Survey of Member Companies

Survey Question: Do all the homeopathic components in your OTC homeopathic drug products meet the OTC attenuation (potency) levels in the HPCUS? (Yes or No)

All 28 companies responded YES.

Based on 28 respondents

Survey of Member Companies

Survey Question: When evaluating label indications for your OTC homeopathic drug products, do you only use indication wording from FDA OTC final or tentative final monographs? Yes or No

Eighteen (64%) responded they use the wording as a guide when evaluating label indications for their OTC homeopathic drug products.

Based on 28 respondents

Survey of Member Companies

Survey Question: If not, what basis do you use to determine if your products are appropriate for OTC sale?

- FDA's CPG400.400 ("self-limiting disease conditions amenable to self-diagnosis") (39%)
- Comparison with non-homeopathic (allopathic) OTC products in the U.S. market (11%)
- FDA warning letters (39%)
- Close adherence to indications listed in homeopathic literature (43%)
- **Adherence to HPUS guidelines (21%)**

Survey of Member Companies

- What constitutes “Adherence to HPUS guidelines” (21%)?
  - *Reminder: 100% adherence to HPUS OTC Safety Guidelines*
  - *Responses refer to HPUS Labeling Document → mainly refer subscribers back to 21 C.F.R. regulations*
  - *Newer Draft HPUS Labeling Document → more extensive guidelines for labeling*

Survey of Member Companies

Survey Question: What other steps do you undertake in considering your marketing of OTC products?

- Published Clinical/Scientific Experience/Trials/Information (29%)
- Consumer study & market research/survey (17%)
- Toxicity study and/or review (incl. Adverse Event Reporting) (31%)
- Marketing authorization for similar product in other countries (24%)
- Internal corporate review & claims study (38%)
- Legal and/or outside consultant review (55%)

AAHP Supports FDA Enforcement Action Against Outlier Products

- Vast majority of OTC homeopathic products are appropriately labeled and comply with FDA and HPUS requirements
- OTC homeopathic drugs, labeled for indications requiring medical intervention, are outlier products
- Outlier products require enforcement action

Mark S. Phillips, Pharm.D.

Treasurer, American Association of Homeopathic Pharmacists

Responding to FDA Questions: Question 8

Do consumers and health care providers have adequate information to make informed decisions about drug products labeled as homeopathic?

- Retail products labeled with information including: Ingredients, Uses, Directions for Use, and Warnings
- Label information presented in Drug Facts format
- HPUS and AAHP guidelines = Products prominently state “Homeopathic” or “Homeopathic Medicine”

Responding to FDA Questions: Question 8

Do consumers and health care providers have adequate information to make informed decisions about drug products labeled as homeopathic?

- AAHP's advertising guideline = Requires disclaimer:

"*These statements have not been reviewed by the Food and Drug Administration*"

Responding to FDA Questions: Question 8

Do consumers and health care providers have adequate information to make informed decisions about drug products labeled as homeopathic?

- As a practicing pharmacist I find that:
  - Manufacturers are increasing consumer access to pharmacists and other health care professionals to answer questions
  - Poison Control Centers are increasing the breadth and depth of their resources to provide information to inquiring consumers and health care professionals

Responding to FDA Questions: Question 8

Do consumers and health care providers have adequate information to make informed decisions about drug products labeled as homeopathic?

- Labeling of homeopathic drugs is informative and helpful for consumers to self-diagnose and self-treat their self-limiting conditions
- Labeling informs consumers when it is appropriate to discontinue use and contact a health care professional
- Consumers are able to understand and make informed decisions about their choices

Conclusion

- Homeopathic CPG 400.400 has record of success
- CPG is workable platform for the regulation of homeopathic drugs
- AAHP is committed partner with FDA in protecting public health

Thank You

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