







The voice of the homeopathic industry.

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4332 SE Logus Road | Milwaukie, OR 97222 www.AAHP.info | t: 513-402-8847



The American Association of Homeopathic Pharmacists is the trade organization of the American homeopathic industry. Our not-for-profit association of homeopathic manufacturers, marketers and pharmacists/individuals represents the main body of manufacturing and distributing companies in the U.S., with connections to other manufacturers overseas. AAHP was founded in 1923 and has decades of experience representing the interests of the homeopathic industry.

The association is a single strong working coalition for the homeopathic market. Numerous specialty product manufacturers provide industry diversity while still contributing to a unified association voice on regulatory and market issues. This alliance of the industry's many participants and their active involvement in our common affairs is an indicator of the health of this growing industry, which is mirrored in continuing sales growth and renewed interest in homeopathic drug products.

AAHP has grown over 95 years from a small group of like-minded pharmacists to an association representing more than half of homeopathic manufacturers and currently over 90 percent of market share for homeopathic medicines in the United States. This growth has come by an emphasis on maintaining and developing product quality and adherence to applicable standards and regulations, through our Compliance Through Education programs.

All persons engaged in the production and distribution of homeopathic drug products have a unique responsibility to the public seeking symptom relief, restoration of health and protection against disease. Professional and individual consumers depend upon our members' integrity to provide safe, reliable, and efficacious products; correct and honest information; and sincere, professional service. Association members pledge to maintain a level of professional competence by promoting training and education, and by respecting the values of competitors and recognizing differences of viewpoint or philosophy.

The members of AAHP support the Principle of Similars; we support the manufacture, distribution, marketing, and sales according to all applicable regulations and guidelines, including but not limited to the Homeopathic Pharmacopoeia of the United States, the Code of Federal Regulations, the FDA Compliance Policy Guide and all appropriate current good manufacturing practices (cGMPs) and labeling requirements. Members concur to manufacture, distribute, market, and sell only those homeopathic drug products that uphold the reputation, integrity, and growth of homeopathy in the United States.

AMERICAN ASSOCIATION OF HOMEOPATHIC PHARMACISTS

VISION:

Founded in 1923, AAHP functions as a trade association within the homeopathic pharmaceutical industry to represent the opinions and interests of homeopathic product manufacturers and distributors.

MISSION	KEY STRATEGIES	MAJOR INITIATIVES
Promote excellence in the practice of homeopathic pharmacy, manufacturing and distribution, and marketing	Educate members regarding the importance of compliance with the good manufacturing, promotion and labeling practices for homeopathic products codified in the HPRS, CFR, Compliance Policy Guides and other applicable regulations	 Actively pursue member input on all projects of the association Align materials with member needs Conduct education seminars, publish newsletter Publish original research and historical writings of the association
Enable effective legislation and the prestige of the industry through positive and productive dialog with lawmakers and regulators	Maintain a high level of awareness of homeopathy and issues of interest to the homeopathic industry among lawmakers and regulators	 Promote voluntary business practice guidelines acceptable to members and regulators Establish relationships with appropriate officials at FDA and FTC Educate regulators and legislators about homeopathy Monitor pending legislation and regulations Anticipate and propose future regulatory models
Enhance the reputation of homeopathic medicines	Conduct educational public relations efforts as well as present findings from original research and new understandings to key stakeholder communities	 Establish research relationships with pharmacy and public health schools Conduct original research that supports the interests of the industry Create awareness for original content via public relations and government affairs activities
Contribute to retailer acceptance and consumer demand for homeopathic medicines	Encourage confidence in and understanding of homeopathic medicines among retailers and consumers	Develop and conduct consumer- focused education campaigns
Facilitate mutually beneficial relationships with leaders and experts in the homeopathic and self-care communities	Establish AAHP as a leader and facilitator within the homeopathic and self-care communities in the United States	 Strengthen relationships with allied associations Become the source for information and knowledge regarding homeopathy Increase membership Increase talent resources available to implement association programs

MEMBER BENEFITS AMERICAN ASSOCIATION OF HOMEOPATHIC PHARMACISTS

AAHP is the leading association for the manufacturers, distributors, and marketers of homeopathic drugs. It's your association. But it's much more than an association. **AAHP Is...**

Your Source for Business Intelligence. AAHP's monthly electronic newsletter, *NetworkNews*, includes member-exclusive articles on crucial and timely topics affecting your business. Recent headlines have included "New Drug Listing Requirements Effective this Month," "Changes Are Coming to Product Labels," and "Homeopathy in the Era of Trump." With AAHP membership, you get custom-tailored industry knowledge you can't get anywhere else.

Your Voice to FDA and FTC. AAHP makes sure FDA and FTC hear our members' perspectives. Most recently, we've been hard at work with FTC and third-party consultants to create proper disclaimer language—a monumental task that would prove too costly for any one company. That's the power of association. AAHP helps to shape market regulations in your favor, saving you the massive amounts of time and money it would take to do it on your own.

Your Agent on Capitol Hill. AAHP fights for your right to market your product. This means working with elected officials. AAHP has a dedicated committee, including seasoned lobbyists, that regularly educates lawmakers on Capitol Hill about our industry and our unique needs. With AAHP membership you can forget hiring your own lobbyist—we have your back covered in our nation's capital.

Your Network Builder. The whole industry comes together at AAHP's semi-annual meetings to network, learn, and share knowledge. Members build valuable relationships—both trusted colleagues and lifelong friends—all while gaining insights from the industry's top professionals and leaders. AAHP membership offers you a seat at the table, building your rolodex and allowing you to shape the direction of the industry.

Your Expert Support. Use the member-exclusive "Ask AAHP" service to receive technical advice and suggestions from board members and other industry experts. In the past, we've received questions like, "Can the word 'homeopathic' be placed anywhere on my label, or is there a place requirement?" and "Based on the HPUS attenuations listed for Arnica montana, is a 1X attenuation acceptable for OTC external use?" Why get an outside consultant for everyday advice when your AAHP is ready to help?

Your Education Hub. AAHP offers a host of webinars and training programs to help your company achieve peak performance. Recent topics have included stability studies for homeopathic products, FDA inspections, and improvements to the homeopathic pharmacopoeia. As a member, you receive significant registration discounts for these one-of-a-kind training sessions.

The AAHP Education Committee presents in-person seminars and real-time webinars. Participants include industry members, scientists, attorneys, regulators and other industry associations. Attendees benefit fromfirst hand knowledge of important scientific, legal and regulatory information and receive valuable tools including checklists, forms and templates for use within their companies. Educational programs are also available on DVD and streaming video.

2018 WEBINAR SCHEDULE:

- O1 George Bernstein on FDA Inspections Review
- Q2 Eric Foxman on HPUS Update
- Q3 (September member meeting) FDA Representative on FDA Draft Guidance Document on Homeopathic Drugs
- Q3 Ryan Gooley of Stericycle on Recalls
- Q4 Pejman Parhami Elements of Quality Systems for a Homeopathic Manufacturer;
 Establishing Drug Specifications; CAPAs

2017 WEBINAR SCHEDULE:

Stability Studies for Homeopathic Products

Special 2 Part Webinar, December 2017

Designed for CEOs and managers responsible for compliance and quality assurance, this webinar will place stability studies within a larger context of product quality—which extends far beyond the simple task of expiration dating. The program will outline the hidden costs of doing business without product stability information as well as ways that manufacturers can use stability findings to create products with competitive advantages. Additionally, attendees will learn what the U.S. Food and Drug Administration expects from homeopathic drug manufacturers and marketers when it comes to drug stability.

2017 HPUS Updates

A Webinar on Homeopathic GMPs and Stability May 2017

The Homeopathic Pharmacopoeia of the United States has posted two new documents to the HPUS. These documents and their guidance information are essential to your business, your cGMP compliance, your products and your long-term success in the market!

FDA Inspections of Homeopathic Manufacturing Facilities: An Agency View December 2016

Led by Tamara Ely, Senior Policy Advisor in the FDA's Office of Manufacturing Quality, the webinar will examine FDA's considerations for inspections regarding compliance in homeopathic drug manufacturing facilities. With case studies and compliance outcomes, the 90-minute program will provide a clear overview of what to expect from an FDA inspection of your facility.



NEWSLETTER

Members receive our industry-leading newsletter. Each month we focus on the issues important to our members and the homeopathic community.



SOCIAL MEDIA

Connect in real-time discussions; and engage with other AAHP members, lobbyists and lawmakers.

Get alerts regarding the latest industry news, information and legistlation.

Share ideas and opinions in a public forum.

Gather opinions on issues important to our industry.



Changes are Coming to Product Labels!

By Alvin J. Lorman, AAHP counsel

Not only are there changes to the Homeopathic Pharmacopeia of the United States (HPUS) on the horizon, but our association's Board of Directors is expected to announce a new advertising disclaimer as well. And there's a wild card in the game...

READ MORE

Homeopathy in the Era of Trump

By Pete Evich, AAHP government relations

The election of Donald Trump and a Republican-controlled Congress will mark a change from the "divided government" norm that has reigned over Washington during the last six years. While the new political environment will be more favorable toward business in general, how this change will specifically impact regulatory policy affecting the homeopathic industry is yet to be known...

Read More

How is Homeopathic Belladonna Made? By Mark Land, AAHP president

Belladonna, more commonly known as deadly nightshade, Atropa belladonna, devil's cherries, and poison black cherry, is a perennial herb that has been valued for its medicinal properties for more than five



Homeopathy in the Era of

How is Homeopathic Belladonna Made?

New Analytical Methods

Intro to HPUS

Trump

Read More

An Introduction to the U.S. Homeopathic Pharmacopoeia

By Mark Land, AAHP president

The Homeopathic Pharmacopoeia of the United States (HPUS) is the legal basis for marketing homeopathic drug products in the United States and many other countries around the world. The HPUS is considered an Official Compendium and drug substances referenced therein are officially recognized as drugs. The importance of the HPUS cannot be overstated for homeopathic manufacturing and marketing organizations

Read More

New Analytical Methods

By Mark Land, AAHP president

When Samuel Hahnemann founded homeopathy at the end of the 18th century, he couldn't have fathomed the extreme capabilities of today's analytical technologies. Most instruments currently used to assess homeopathic dilutions can resolve to less than one part per million. Next-generation technologies currently on the market



can now resolve to parts per billion! How are these ultrasensitive analytical methods affecting our industry?

Read More

JOIN NOW

STAY CONNECTED fin





ASSOCIATION OF
HOMEOPATHIC
PHARMACISTS

MERICAN

Last year was a busy year for AAHP. With a new administration in the White House and key legislative issues heating up, the association had a full agenda. Together with our members, we made great strides in protecting our industry and bettering our businesses.



"Successfully represented and defended the industry on Capitol Hill."

- Developed a label disclaimer statement responsive to FTC's November 2016 enforcement policy. AAHP met with the FTC, developed a research protocol, created and tested disclaimer language and presented it to the FTC. The standardized statement provides protection against regulatory and litigation risks. If taken on individually, this project would have cost each member about \$100,000.
- Welcomed **three new members**: Energetix, Inc., Forces of Nature, and Natural Ophthalmics, Inc.
- In conjunction with our lobbyist, **visited 15 legislators on Capitol Hill more than 22 times** to promote a positive regulatory climate for our products. In one crucial outcome, AAHP successfully garnered support from U.S. Sen. Bob Casey of Pennsylvania toward transparent development of FDA's guidance for homeopathic drug products.
- Successfully defended the industry against unintended consequences of OTC monograph reform. AAHP monitored and advised lawmakers on provisions of OTC monograph reform legislation that would have subjected homeopathic manufacturers to user fees.
- Regularly updated members on hotbutton legislative issues such as new/revised FDA guidance, California "false advertising" litigation, cGMP compliance, finished product testing, and the FDA User Reauthorization Bill.
- Wrote and shared **46 articles** on regulatory issues, compliance and manufacturing best practices, password-protecting some of the most crucial information for members only.
- Distributed monthly *NetworkNews* e-newsletters. A recent survey of readership found that nearly **80 percent of respondents consider the information to be useful** or very useful, while more than 70 percent feel more informed about regulatory issues affecting their business after reading the newsletters.

- Educated more than 100 individuals from over 40 companies through the 2017 Compliance Thru Education webinar series. Topics included pharmacovigilance, HPUS updates and a two-part series on drug stability studies.
- Gathered members to learn about new, hypersensitive **technologies**, recently used by the FDA, that can analyze homeopathic dilutions down to the parts-per-billion level.
- Held two successful membership meetings that **united industry leaders** in sharing best practices, learning the latest regulatory news, and networking with peers.
- **Shared our industry's positive story** through press releases, garnering coverage in publications such as *Natural Practitioner* and *Vitamin Retailer*.
- To increase momentum leading up to AAHP's 100th anniversary in 2023, engaged in **strategic planning** and also surveyed the membership for feedback on future projects and priorities.
- Began a research and planning initiative for future **grassroots campaigns**.
- Mobilized volunteer leadership, harnessing their unique skills during monthly Board
 of Directors meetings, twice monthly Legal and Regulatory Committee meetings as well
 as meetings of the Business Development Committee, Education Committee and Editorial
 Committee.
- Provided representation in the Homeopathic Action Alliance, a coalition of homeopathic organizations that strengthens community and provides **a unified face for homeopathy**.

"Successfully gained support from U.S. senators toward transparent development of FDA's guidance for homeopathic drug products."



ORRIN G. HATCH

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Website hatch senate gov



WASHINGTON, DC 20510-4402

PRESIDENT PRO TEMPORE

COMMITTEES:

FINANCE

JUDICIARY

HEALTH, EDUCATION. LABOR, AND PENSIONS

AGING

JOINT COMMITTEE

December 13, 2017

Scott Gottlieb, M.D. Commissioner U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993-002

Dear Dr. Gottlieb:

We write in response to the February announcement by the Center for Drug Evaluation and Research (CDER) to inquire about your 2017 agenda for publishing new and revised draft guidance documents, which includes guidance on "Drugs Labeled as Homeopathic." There has been a Food and Drug Administration (FDA) guidance document covering homeopathic drugs since 1988, so presumably this would be a revision of that guidance.

Homeopathic drugs have been recognized as drugs since the original Food, Drug, and Cosmetic Act of 1938. In the 1980s, FDA worked collaboratively with the homeopathic community to develop a workable regulatory framework for the marketing of homeopathic products since FDA specifically excluded them from the Over-the-Counter (OTC) Drug Review. This collaboration resulted in FDA Compliance Policy Guide (CPG) 400.400, "Conditions Under Which Homeopathic Drugs May Be Marketed."

FDA held a two-day public hearing in April 2015, to examine the status of the CPG after over 25 years of operation. FDA sought and received broad public input on the agency's existing regulatory framework for OTC homeopathic drug products. By placing the guidance on homeopathic drugs on CDER's agenda, FDA has another opportunity to collaborate with stakeholders and put forth its intent on these products.

We fully support the agency's mission to review its existing regulations and guidelines to ensure they are sufficient to protect the public health. We also strongly support collective engagement between the regulator and the regulated community. We urge CDER to involve, as appropriate, the regulated stakeholders in its process of developing new or revised draft guidance for OTC homeopathic drug products.

Lastly, regarding the process, we anticipate that with a guidance document of this significance, CDER intends to issue this as Level 1 guidance, which affords the opportunity for public comment before a final guidance is published. If this is not the case, we urge you to reconsider, as public and stakeholder engagement produce long-lasting results.

We appreciate your commitment to ensuring quality and safe drug products for U.S. consumers and we look forward to your response.

Sincerely,

Orrin G. Hatch U.S. Senator

Martin Heinrich U.S. Senator

ROBERT P. CASEY, JR.
PENNSYLVANIA

AGRICULTURE, NUTRITION,
AND FORESTRY
FINANCE
HEALTH, EDUCATION,
LABOR, AND PENSIONS
SPECIAL COMMITTEE ON AGING

JOINT ECONOMIC



WASHINGTON, DC 20510

October 31, 2017

Scott Gottlieb, MD Commissioner United States Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, Maryland 20993-0002

Dear Commissioner Gottlieb:

I write today to inquire about the February announcement by the Center for Drug Evaluation and Research (CDER) with respect to the Center's 2017 agenda for publishing new and revised draft guidance documents, which includes guidance on "Drugs Labeled as Homeopathic."

I understand that the existing regulatory framework for homeopathic drugs, the Food and Drug Administration (FDA) Compliance Policy Guide (CPG) 400.400, "Conditions Under Which Homeopathic Drugs May Be Marketed," has been in place since the 1980s, and that in 2015 the FDA held a public hearing to solicit feedback from the public on the regulation of homeopathic drugs. However, since that meeting, no changes have been made to the CPG.

Should FDA move to alter or amend any guidance relating to homeopathic drugs, I respectfully request that you consider the feedback provided during the public hearing in 2015, and provide an open and transparent process that includes the opportunity for stakeholders to provide comments on any proposed changes to the existing guidance. Additionally, I ask that you provide my office with updates on any future announcements relating to changes to the guidance for homeopathic drugs.

Thank you for your continued commitment to ensuring the safety of the drug supply. If you or your staff have any questions about this matter, please contact my Legislative Assistant, Sara Maskornick, at 202-224-6324 or sara_maskornick@casey.senate.gov.

Sincerely,

Robert P. Casey, Jr.

United States Senator

Join Us.

Together, we are the voice of the homeopathic industry.

Contact us today!

513-402-8847

email: info@aahp.info



4332 SE Logus Road | Milwaukie, OR 97222 www.AAHP.info | t: 513-402-8847



American Association of Homeopathic Pharmacists 4332 SE Logus Road • Milwaukie, OR 97222 Ans Serv: 513-402-8847

Email: info@aahop.info
Website: www.TheAAHP.org

MEMBERSHIP APPLICATION

Firm Name:				
Name & Title	of Representative to			
AAHP: Addre	ss:			
City:		State:	_ Zip:	Country:
Telephone: _			_ Fax:	
There are thr	ree categories of mem	bership:		
homeopathic Number) and distribution o the core of th development active annual	drug products (and wall that engage in one of selling of homeopations AAHP mission: prorand appropriate regulations to the H	when required, m or more of the fol hic drug product motion of excelle latory oversight. lomeopathic Pha	aintain a current lowing activities s. This is the ma nce in homeopa Voting Member rmacopeia of the	erate a facility in the U.S. for at FDA Establishment Registration in the U.S.: manufacturer, ajority of members and represents athic manufacturing, market are required to maintain an e United States (www.hpus.com).
companies th	•	consulting to th	•	athic industry. Examples include industry, or foreign entities not
manufacturin member may	g, distribution, marke	eting or selling ho	omeopathic drug er-eligible corpo	omeopathy as it relates to g products. However, an individual orate entity, unless that corporate person.
Application	n for Membership	Туре:		
	Voting Membership			
	Affiliate Membership)		
	Associate Membersh	•		
VOTING 25	A AFETI TATE Man	nhar Annlican	te nleace and	wer auestions 1-24

ASSOCIATE Member Applicants, please answer questions 19-25.

1. Name of CEO/President:			
2. Email (designated representative):			
Other email (others in firm to			
receive AAHP communications)			
Name of officer responsible for (one or more of the fo	llowing):		
Regulatory Affairs	email		
Quality Assurance	email		
Manufacturing	email		
3. Year Firm Established:			
4.State/Country Established:			
Incorporated? Y N			
Public? Y N			
Private? Y N			
5. Specify the firm's primary business activities: (Ch	neck all that apply.)		
Manufacturing Repackaging			
Distributing Marketing			
Research Consulting to Industry			
☐ Service Provider ☐ Other			
6. Number of years firm has been manufacturing / s consulting/ service to homeopathic industry?	elling homeopathic ph	narmaceı	uticals or providing
7. Is the firm's facility under the jurisdiction of the $\mbox{\it Ur}$	nited States? γ	N	
8. Does the firm have an FDA Establishment Registra	tion Number? Y	N	
If yes, include a copy of FDA Establishment Regis	tration.		
9. State License Number:			
10. If no Establishment Registration Number or state IRS EIN Number:	license, then Busines	s License	e Number:
11. Does the firm have a proprietary line of homeopa United States? Y N	thic drug products the	at is mar	keted in the
12. If yes, please list the trademark(s) under which t	he products are mark	eted:	
13. Which of the following product types are manufac	ctured or sold by the f	irm? <i>(Ch</i>	neck all that apply.)
☐ Single-ingredient homeopathic drug products			Rx
Combination-ingredient homeopathic drug pro	oducts		ОТС
Other:			

14.	То	which markets	does	the firm sell? (Ch	eck all that apply.)	
		Natural Foods				
	Ц	Export	∟ P	rivate Label		
		Other:				
15	In	which of the cor	nmo	n dosage forms is	the firm interested? (Check all that apply.)	
		Tablets		Pellets		
		Liquids		Parenterals		
		Topicals		Nasal Sprays		
		Ophthalmics		Other		
16.		ease include <u>sam</u> peling.	ples	of five different r	epresentative homeopathic drug product	
<i>17</i> .	Ple ing	ease include a pr gredients (may b	oduc e an	t catalog or list sh electronic file or l	nowing all product names, label indications and ink to $\overline{\text{we}}$	
18.	Lis	st all websites ov	vned	by company:		
19	9. How did you become aware of or interested in AAHP?					
20	20. Briefly state the reason you wish to join AAHP:					
21	Of	the 2-3 membe	rship	meetings each ye	ear, how many could you attend?	
22	Lis	st other homeop	athic	organization affili	ations:	
	Na	tional Center for	Hon	neopathy		
	So	ciety for Ultramo	olecu	lar Medicine		
	Sta	ate or regional h	ome	pathic society	(specify)	
	Otl	ner homeopathic	orga	anization(s)	(specify)	
23	WI	hat other busine	ss or	professional orga	nization(s) are you a member of or affiliated with:	
24	Th	is profile will hel	p all		of your company or homeopathic activities and interests. better acquainted with each other, and may be included it its membership.	
25	As	sociate member	s, pl	ease include a <u>cop</u>	oy of your state pharmacist's license (if applicable).	
In	the	event additiona	l info	rmation is needed	I, a member of the Board of Directors will contact you.	

American Association of Homeopathic Pharmacists Members' Pledge

Through our membership in the AAHP, we want to work with others to further the missions of the association: promoting excellence in the practice of homeopathic pharmacy, manufacturing, and distribution; providing opportunities for market development and market growth; maintaining an appropriate regulatory and legislative climate; providing outreach; promoting efforts to build a coalition with all interested parties within the homeopathic community.

We support the AAHP by upholding the spirit and intent of the association's Code of Ethics: supporting the Principle of Similars, the primary foundation of homeopathy; supporting the manufacture, distribution, marketing and sales of homeopathic drug products according to all applicable regulations; maintaining a level of professional competence by promoting training and education; respecting the values of competitors, and recognizing difference of viewpoint or philosophy; acting with honesty, integrity, and sincerity in all professional relationships; upholding the reputation, integrity, and growth of homeopathy in the United States; and using accurate information and fair balance to conduct our marketing activities.

We wish to keep informed and continually educate ourselves and our staff of regulatory changes. Our company intends to work towards and maintain compliance with all applicable state and federal regulations for homeopathic drug products.

Signature:	Date:			
Name:	Title:	Title:		
Voting Member companies are required to Homeopathic Pharmacopeia of				
Please submit completed and signed payment to: American Associa 4332 S.E. Logus Roa	application, along with attaction of Homeopathic Pharrad, Milwaukie, OR 97222	achments and nacists		
Dues for 2020 (Payable in U.S. Dollars)				
Please see membership definitions or	n page 1.			
☐ Voting Member based on self-report	ed annual			
sales (Please check appropriate level.)	Sales Level (\$)	Dues (USD)		
	☐ \$75-100 Million	\$60,000		
	☐ \$50-75 Million	\$55,00 <u>0</u>		
	☐ \$30-50 Million	\$38,500		
	□ \$20-30 Million	\$29,300		
	☐ \$10-20 Million	\$18,700		
	□ \$5-10 Million	\$13,400		
	☐ \$3-5 Million	\$9,000		
☐ Affiliate Member: \$2,500	☐ \$1-3 Million			
☐ Associate Member: \$2,000	☐ \$600K-1 Million	\$3,050		
= A330ciate Fichiber: \$200	□ \$300-600K	\$2,000		
	□ <\$300K	\$1,000		