A Product Theater, a sales / marketing presentation on your product or service, is the ultimate opportunity to deliver your message to attendees at the American Headache Society (AHS) Scottsdale Headache Symposium. Exhibitors are given the opportunity to present either a 30-minute or 60-minute Product Theater. To maximize attendance, presentations are scheduled without conflict of other Product Theaters. The Product Theater will be advertised in the AHS Final Program, Meeting Event App and be listed on signage. These non-CME presentations allow you to showcase your product or service, however, they must remain within FDA guidelines. The Product Theater presentations are done in a designated area outside of the Exhibit Hall.

<table>
<thead>
<tr>
<th>60-minute Product Theater</th>
<th>Cost: $20,000 each</th>
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</thead>
<tbody>
<tr>
<td>30-minute Product Theater</td>
<td>Cost: $10,000 each</td>
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</tbody>
</table>

The Product Theater support package includes:

- Room set in classroom or theater style (for maximum attendance). Room set is dictated by AHS due to multiple room use. Any changes to the room set may result in set-up fees and are the responsibility of the Product Theater sponsor company.
- Pre-show promotion support to include pre-registrant mailing list (one time use), attendee registration bag insert, hotel room drop (arrangements and any hotel fees associated with room drop are the responsibility of the sponsoring company). AHS must approve all materials prior to finalization. The pre-registrant list is seeded for control. Unauthorized use of the mailing list will result in an additional fee of $1,000 and restriction on any further use. Email addresses are not provided.

Each Product Theater sponsor is responsible for the following:

- Providing presentation title, content information, presenter(s) name(s) and a summary of the Product Theater for inclusion in the Final Program. Information must be received no later than September 15, 2017 for inclusion in the Final Program.
- Food service, if offered, will be arranged with the JW Marriott Desert Ridge Resort and will be at the expense of the sponsoring company. Outside food and beverage is prohibited.
- AV equipment, if needed, will be arranged by sponsoring company. AHS has contracted with GRUV Audio Visual. You are free to use your own AV vendor, however, coordination of room set-up, etc., must be done with GRUV Audio Visual.

**Availability (only one application will be accepted per company)**

<table>
<thead>
<tr>
<th>Select</th>
<th>Date</th>
<th>Regular Product Theater</th>
</tr>
</thead>
<tbody>
<tr>
<td>Friday, November 17, 2017</td>
<td>12:45pm – 1:15pm</td>
<td></td>
</tr>
<tr>
<td>Saturday, November 18, 2017</td>
<td>12:30pm – 1:30pm</td>
<td></td>
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</table>
Ownership
Copyright of the content presented at the Product Theater shall be owned by the Product Theater sponsor with all rights intact. The Product Theater sponsor is responsible for obtaining copyright permissions for previously copyrighted materials that will be part of the Product Theater presentation.

PRODUCT THEATER PRESENTATION INFORMATION

Product Theater Title

Name and Description of Product / Service / Treatment

Name of Presenters (please include affiliation) REQUIRED

Name: __________________________ Affiliation: __________________________

Name: __________________________ Affiliation: __________________________

Name: __________________________ Affiliation: __________________________

Summary of Presentation
Please provide a description of the evaluation process and expected outcomes. The AHS must receive program title, description and proposed speakers, along with the program agenda no later than August 15, 2017.
PRODUCT THEATER APPLICATION

Company: __________________________________________________________

Contact Name: _____________________________________________________

Address: ___________________________________________________________

City / State / Zip: ____________________________________________________

Phone: ___________________________ Fax: ________________________________

Email: _____________________________________________________________

Payment Information

Amount $ ______________________

☐ Payment will be made via check, payable to the American Headache Society, in US Funds and drawn on a US bank.

☐ Payment will be via credit card ☐ American Express ☐ Visa ☐ MasterCard

Account Number ____________________________ Exp. Date ________________

Name on Card _______________________________________________________

Signature ____________________________ Date _______________________

APPLICATION DUE DATE: AUGUST 15, 2017

Please return this form along with payment to:
American Headache Society
19 Mantua Road ● Mt. Royal, NJ 08061
AHSHQ@talley.com ● Fax: 856-423-3420

Confirmation notifications will be emailed no later than August 31, 2017
PRODUCT THEATER GUIDELINES

AHS 2017 PRODUCT THEATER REGULATIONS, TERMS AND CONDITIONS

For the purposes of this agreement, “Exhibitor’ is defined as the exhibiting company participating in a product theater presentation.

1. Only current AHS meeting exhibitors and sponsors are eligible to submit a Product Theater Contract and Application for consideration.

2. Exhibitors must provide AHS with a copy of the program outline/summary, session title and presenter names and credentials along with the completed Product Theater Contract and Application by August 15, 2017. Applications received after the deadline will not be considered. This is for review purposes. Hands-on courses will not be permitted.

3. The Product Theaters are not eligible for CME, CEU or CDE under the ACCME guidelines. Product Theaters are not a part of the Scottsdale Headache Symposium of the AHS Meeting and cannot be represented as such in Exhibitor promotional materials.

4. Product Theaters are considered ‘unofficial’ programs (not supported by AHS). Therefore, there can be no implications in any promotional materials, mailers, or during these events, that the Product Theater is connected with the Scottsdale Headache Symposium program, presented in cooperation with the Scottsdale Headache Symposium, or endorsed by AHS. In describing these events, you may not use phrases such as “presented during,” “presented in conjunction with,” “preceding,” or “prior to” the Scottsdale Headache Symposium program. The use of Society names, logos or seals is strictly prohibited. All Product Theater promotional material MUST include the following statement:

   This program content and the views expressed therein are those of the presenting corporate entity and not of the AHS. This program is not an official part of the AHS Scottsdale Headache Symposium.

5. The Exhibitor Relations Committee and/or the Program Planning Committee Chair(s) will review submitted program outlines and participating exhibitors will be notified of their acceptance to host a product theaters.

6. An invoice will be sent upon acceptance of a product theater. Full payment is due upon receipt of the invoice. Please make checks payable to AHS (American Headache Society). No refunds will be given after notification of acceptance by AHS.

7. AHS will allow (3) three promotional signs at the meeting. All signs must measure 22” high by 28” wide. One (1) sign may be placed at the satellite session registration area 24-hours prior to the approved time for the satellite sessions, one (1) sign may be placed outside the door of the meeting room of the satellite sessions and one (1) sign may be placed in the AHS registration area. Handheld signs and/or sandwich boards are prohibited.

8. Upon request and approval of promotion material, AHS will e-mail each host company the meeting attendee list to assist companies with their promotional efforts. This list will be available approximately 4-6 weeks prior to the meeting. Companies are prohibited from using the AHS logo in their promotional materials. Only registered attendees of the AHS Scottsdale Headache Symposium are permitted to attend the Product Theater.
9. Exhibiting company representatives of the session planning entity may not be present in public spaces prior to the session start time.

10. Product Theater hosts are responsible for any expenses related to food and beverage and audiovisual charges incurred.

11. AHS is not responsible for and does not guarantee attendance at the Product Theater. The host company is responsible for promotion. We encourage additional marketing of your Product Theater. AHS will provide a list of pre-registered attendees, only upon request and after approval of promotional material.

12. Per the Food and Drug Administration (FDA), any mention of pharmaceutical product names that is accompanied by information on use and indications will be viewed as a product advertisement and must comply with the full disclosure requirements. AHS is not responsible in any way for scientific or promotional content. It is recommended that all sponsoring exhibiting firms familiarize themselves with the FDA requirements to avoid being penalized by the FDA. See included FDA Fact Sheet.

13. Session Final Program content is subject to editing for clarity. The following template should be followed when submitting information for the Final Program. Final Program listing is due no later than September 15, 2017.

   Session Title

   Session Description (75-word maximum)

   Faculty list (Fname Lname, Credentials)

   Program sponsored by NAME. This promotional activity is not certified for CME credit.

14. All matters not specifically covered in the preceding regulations shall be subject solely to the decision of AHS. Unethical conduct or infraction of these rules by the sponsoring company or its contracted representatives will, without limitation of other sanctions, be subject to dismissal from the Product Theater area. If such happens, no refund will be made, and the sponsoring company and/or its representatives will make no demands for redress. It is the responsibility of the sponsoring company representative contracting for a Product Theater to notify all on-site firm personnel of these regulations and ensure compliance herewith.

15. The sponsor assumes full responsibility for its equipment, merchandise, displays and its Product Theater premises during set-up, maintenance, occupancy and removal thereof. In addition, the sponsor shall be responsible for its own acts, errors and omissions, as well as any representations, warranties and agreements, made in conducting the Product Theater and the performance of this contract. Sponsor’s responsibility shall include, but shall not be limited to, any injury or damage caused by or arising out of any work performed by the sponsor or its employees or any person hired by the sponsor or the failure of sponsor’s equipment, defects in the premises caused by the sponsor or its employees or any person hired by the sponsor, or any sale or service of food and beverages by the sponsor.

16. The sponsor shall indemnify, hold harmless and defend the AHS, any employed security service, JW Marriott Desert Ridge Resort and their respective trustees, directors, officers, employees and agents, and each of them (collectively referred to as “Indemnities”), from and against any and all demands, claims, causes of action, injury to persons or damage to property, liabilities, fines, penalties, costs and expenses, including reasonable attorney fees and litigation costs up through and including any appeal, arising solely out of or caused by the sponsor’s
negligent or willful acts, errors or omissions or failure of performance in connection with the product theater as contemplated by these regulations, terms and conditions. The terms of this indemnification shall survive the termination or expiration of the Product Theater contract.

17. The sponsor, at its own expense, shall carry adequate liability and other insurance protecting itself against any claims arising from any activities it conducts during or related to the Product Theater. All such insurance shall be with a carrier or carriers authorized to do business in the State of Arizona release the sponsor from or limit the sponsor’s obligations to protect, indemnify, hold harmless and defend the Indemnities as required by these regulations. Proof of this insurance will be made available to AHS upon request.
FDA Regulation of Product Promotional Activities

*Industry’s sponsorship of FDA-regulated product promotional activities should not be confused with their financial support for independent continuing medical education*

As part of marketing and sales operational plans, pharmaceutical, biotechnology and medical device companies provide healthcare professionals the opportunity to learn about a company’s products or disease states of interest through industry-developed, U.S. Food and Drug Administration (FDA)-regulated promotional activities. The pharmaceutical, biotechnology and device companies have an obligation and an important role to play in informing healthcare professionals about the availability, safety and effectiveness of medications, vaccines and devices they produce. Accordingly, the timely and appropriate dissemination of information consistent with the FDA-approved product labeling is important if healthcare professionals are to have access to the latest information for use in the treatment of their patients. The content of “promotional information” is controlled by the pharmaceutical, biotechnology, or device company as mandated by the FDA and is distinct and separate from industry support for independent certified continuing medical education (CME). The facts regarding commercial support for independent certified CME are described in a previously published Fact Sheet titled *Pharmaceutical, Biotechnology and Medical Device Company Support of Continuing Medical Education*.

☐ The FDA regulates the marketing of pharmaceutical products and medical devices and permits promotion of these products by drug and device manufacturers to the indications that it has approved. These are often referred to as “on label” indications or “approved uses”. FDA-approved uses of prescription drugs and medical devices are specific with respect to medical condition and dosage or application of the regulated product. The FDA product approval and monitoring systems have an impact on the processes for development and review and the content and delivery mechanisms for all promotion of regulated products.¹

☐ FDA-regulated promotional activities are defined as those activities over which the sponsoring company (manufacturer) has both control of and responsibility for the content.² Such activities often focus on one product, or device, from a company including the latest science within labeling and FDA-approved uses. The roles and responsibilities for faculty participation in these activities are determined by the FDA regulations that control dissemination of promotional product information. For reasons of compliance, faculty are described as being an agent of company, paid directly by company; presenting content developed or approved by company; and limited to proactively discussing only information they provide in compliance with the FDA-approved label for the product. For example, faculty speaking for a company at an FDA-regulated activity are bound by the same FDA regulations that govern a sales representative detailing a physician.³

☐ Content for FDA-regulated promotional activities undergoes a review by the organization’s medical, legal and regulatory staff to ensure medical accuracy, regulatory compliance with FDA-approved labeling and to achieve a balanced presentation of both the benefits and the risks associated with the advertised product.³ Once approved, the information may be proactively communicated by the company or expert faculty contracted by the company and acting on its behalf.

Experts involved in FDA-regulated promotional activities need to be trained on the subject matter, should clearly identify the company that is sponsoring the presentation, acknowledge the fact that they are presenting on behalf of the company, and that they are presenting information that is consistent with FDA guidelines.³
FDA-regulated promotional activities directly sponsored by industry may include dinner / speaker informational programs hosted by the organization’s sales representative at a local restaurant, company branded web sites, the company’s sales and advertising promotional materials, and other activities such as exhibits, product theatres and disease state programs that may be held in conjunction with a medical organization such as a specialty society or state medical association. The US Department of Health and Human Services, Food and Drug Administration stated the following: “Two important sources of information on therapeutic products [human and animal drugs, biological products, and medical devices regulated by the Food and Drug Administration (FDA) for health care professionals] are: (1) activities (programs and materials) performed by, or on behalf of, the companies that market the products, and (2) activities, supported by companies, that are otherwise independent from the promotional influence of the supporting company. Although both provide valuable and sometimes vital information to health care professionals, the programs and materials performed and disseminated by the companies are subject to labeling and advertising provisions of the Federal Food, Drug, and Cosmetic Act, whereas the independent and non-promotional industry-supported activities have not been subject to FDA regulation.”

FDA-regulated promotional activities provide industry with a venue for sharing approved product information based on safety and efficacy data of their products with the goal of increasing appropriate use in the appropriate patients. Physicians and other health care professionals need the most current product information as they consider options for the care of their patients. According to the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, “Appropriate marketing of medicines ensures that patients have access to the products they need and that the products are used correctly for maximum patient benefit. Our relationships with healthcare professionals are critical to achieving these goals because they enable us to – inform healthcare professionals about the benefits and risks of our products to help advance appropriate patient use, provide scientific and educational information, support medical research and education, and obtain feedback and advice about our products through consultation with medical experts.”

References: