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August 26, 2016

Pharmaceutical Research and Manufacturers of America
950 F Street, NW, Suite 300
Washington, DC 20004

Consumer Healthcare Products Association
900 19th Street, NW, Suite 700
Washington, DC 20006

Generic Pharmaceutical Association
777 6th Street, NW, Suite 510
Washington, DC 20001

Advanced Medical Technology Association
701 Pennsylvania Avenue, Suite 800
Washington, DC 20004

Biotechnology Innovation Organization
1201 Maryland Avenue, SW, Suite 900
Washington, DC 20024

EVALUATION OF PLANS FOR EDUCATION AND OUTREACH CAMPAIGN, QUARTERLY TAKE-BACK DAYS, AND BENCHMARKS AND OUTCOME MEASUREMENTS

The Extended Producer Responsibility Working Group (Workgroup) has evaluated the revised plans submitted on August 12, 2016. Based on the requirements specified in the Board Motion adopted on June 14, 2016, our communications to you dated June 29, 2016 and July 26, 2016, the plans were not approved. Attached are the Plan Correction Sheets that were used in our evaluation. They identify each requirement and whether or not the plan **met**, **partially met**, or **did not meet** the requirements. They also provide recommendations for how you can strengthen your proposal prior to resubmittal.

Overall, the plans did not specifically target the County unincorporated communities and lacked sufficient detail and specificity. The focus of the June 14, Board Motion-Option 1 was for industry to conduct a public education and outreach campaign and to host quarterly collection take-back events in the unincorporated communities. Additionally, the motion requires the Workgroup to provide a final report evaluating the implementation of these activities including benchmarks that measure their effectiveness. Each plan was evaluated based on this direction from the Board, and in each case, the plans did not demonstrate how these objectives would be met. Upon resubmission, it is important that you focus your public education and outreach activities on the unincorporated communities (approximately 300,000 households); the take-back event days in the 10 specified unincorporated communities; and the benchmarks that measure the effectiveness of the two plans. The reevaluation will rely on you providing sufficient information, including the specific details required to thoroughly evaluate the plans.

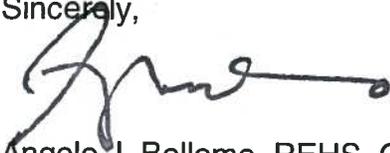
Additionally, we understand that the Sheriff's Department does not want to be responsible for organizing, facilitating or managing the take-back event days in the unincorporated areas, nor do they want to participate in the transfer, storage and destruction of the pharmaceutical and sharps waste, and therefore have declined your grant offer. Our understanding is that the Sheriff's involvement will be limited to overseeing collection at the take-back events in the 10 selected unincorporated communities. Note, the Sheriff's role at take-back events is separate and apart from the collection kiosks available to the public at their 21 Sheriff's station which the Sheriff intends to maintain. Having the Sheriff assume the level of responsibility suggested in your plan was not the expressed intent of the Board Motion or Option 1.

Note, we do not see the Sheriff's position as a deterrent to your ability to meet the Board's intention for industry-led collection events as there are other options available to you to meet this responsibility. Based on our knowledge of how industry-led collection events are handled in other counties, you may want to contract with a pharmaceutical reverse distributor and sharps waste collector, such as Stericycle and others, to conduct such events. Although the Sheriff's Department will not be conducting the collection events on your behalf, they, like the Departments of Public Works and Public Health, remain committed to providing oversight and monitoring of the events, upon agreement for cost reimbursement to these Departments.

Also, thank you for providing the list of agencies and non-profit/CBO partners. It appears that many of these potential partners do not provide services in the County unincorporated communities. Given the direction from the Board, please let us know how these partners will help you provide outreach and education to residents in the unincorporated communities and/or how they will assist with industry-organized take-back event days.

Lastly, we have tried to present the plan review and correction sheets in a clear, easy to use format and hope they facilitate a quick turn-around time for resubmission. If you have questions or need additional information regarding your resubmission, we are glad to assist. We have been in contact with Mr. Hal Dash and are available for a teleconference if you think this would be helpful. If you would like to schedule a teleconference or have questions please contact Ms. Jacqueline E. Taylor, Director of Environmental Protection Branch at (626) 430-5270, or by email at jactaylor@ph.lacounty.gov.

Sincerely,



Angelo J. Bellomo, REHS, QEP
Deputy Director for Health Protection

AJB:mp

c: Board of Supervisors
EPR Working Group
County Sustainability Council
Hal Dash

Attachments

PHARMACEUTICAL AND SHARPS PROGRAM - PLAN CORRECTION SHEET

EDUCATION AND OUTREACH CAMPAIGN PLAN

CONTENT OF MESSAGE

Education and outreach materials requires the following messages:

Met	Partial	Not met	Requirements	Reasons for <i>Partial or Not Met</i>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Promotes and educates residents concerning safe in-home storage ¹	Information provided not specific to Unincorporated Communities (UCs) and it is not clear how the message content will address different demographics.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Describes where and how to return unwanted pharmaceuticals and sharps ¹	Needs specific options/locations in the UCs
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Focused on promoting the collection events as key element ²	Messages should primarily promote quarterly take-back events that industry will be organizing to comply with the Board order
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Expressly discourages disposal of unwanted medicines and sharps in the trash or through a plumbing or septic system ¹	Include language that expressly discourages disposal of medicines and sharps in the trash or down the drain and remove reference to "other methods of disposal available via the DEA, FDA, and EPA websites."
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Provides instructions on the types of materials that will be considered acceptable/unacceptable at the takeback events ¹	Information not provided
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Instructs residents on how to package their unwanted pharmaceuticals and sharps to bring to the takeback events ¹	Information not provided
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Instructs residents how to remove information from pharmaceutical and sharps packaging to maintain their privacy ¹	Information not provided
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Provides schedule of upcoming collection events ²	Specific information missing
SECTION COMMENTS:		<p>Education and Outreach material should:</p> <ol style="list-style-type: none"> Expressly discourage stockpiling Instruct residents to recycle drugs and sharps packaging to the extent feasible <p>Specific message content should be provided for County review.</p> <p>Recommend changing language in Messaging Framework attachment:</p> <ul style="list-style-type: none"> Targeted Audience is Los Angeles County unincorporated areas residents; #1 Disposal sites should list specific locations; In-Home Drug Disposal should exclude DEA, FDA and EPA websites; and should list specific community collection programs in the UAs, (first column last box). #3 Safety/Adherence/Storage - Change "Expired and unwanted medicines and sharps should be used, stored or disposed of with care" to "Expired and unwanted medicines and sharps should be disposed of properly". 		

¹DPH letter to Industry dated 6/29/16

²DPH email to Industry dated 7/26/16

³Industry's Proposal "Los Angeles County Pharmaceutical & Sharps Safe Disposal Education Initiative"

PHARMACEUTICAL AND SHARPS PROGRAM - PLAN CORRECTION SHEET

EDUCATION AND OUTREACH CAMPAIGN PLAN

MESSAGE CLARITY AND LANGUAGES

Education and outreach materials requires the following:

Met	Partial	Not met	Requirements	Reasons for <i>Partial or Not Met</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Utilizes plain language and explanatory images so as to be readily understandable by all residents, including individuals with limited English proficiency ¹	Plan does not state that it will use plain language and explanatory images
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Will be provided in English, Spanish, and other languages as determined appropriate by the Director of Public Health ¹	
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Specific message content and final drafts of education and outreach materials will be provided to Director of Public Health for review prior to dissemination ²	Plan does not state that final drafts will be provided for review prior to dissemination
SECTION COMMENTS:		If resources permit, recommend providing education and outreach materials in Chinese for the Valinda Corridor and South San Gabriel UCs.		

DISTRIBUTION OF MESSAGE

Education and outreach materials plan requires the following:

Met	Partial	Not met	Requirements	Reasons for <i>Partial or Not Met</i>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Describes the various methods/platforms for distribution (Media, Print, Displays, Social Media, Website) to the UCs ¹	Not specific to Unincorporated Communities (UCs)
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Targets the estimated 300,000 UC households and promotes industry's quarterly take-back events ¹	Information not provided
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Will provide materials to pharmacies, retailers of covered drugs and sharps, health care practitioners, health care facilities, veterinary facilities, and other prescribers in the UCs ³	Mentions partnering with these groups - does not commit to providing materials
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Establishes a single website ³	
SECTION COMMENTS:		<p>Provide specifics on how outreach/education will be provided to unique demographic populations (i.e., seniors, adolescents, ethnic groups).</p> <p>Clarify the sentence on page 2 of plan under STAKEHOLDERS: "Partner with chain drug stores.... and others to <u>get</u> (?) consumers information when they pick up their medicines...". Are these partners getting information or are they giving information, or both?</p> <p>Most of the organizations listed in Attachment 2 to support messaging do not serve the targeted unincorporated areas. List should be provided of specific CBOs that serve the unincorporated areas.</p> <p>List specific health fairs and events serving the unincorporated areas that will be utilized for message distribution.</p>		

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EDUCATION AND OUTREACH CAMPAIGN PLAN

	<p>Recommend providing the frequency, quantities, and time periods for each distribution method.</p> <p>Recommend that a toll-free telephone number be established and promoted in the education and outreach plan, primarily providing information on the industry's take-back events.</p>
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TIMELINES

Education and outreach plan requires the following:

Met	Partial	Not met	Requirements	Reasons for <i>Partial or Not Met</i>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Provides timelines for the start/implementation of each element of the plan. For example, when will print advertising begin and end.	Specific information missing
SECTION		Timelines should be realistic and provide more details		
COMMENTS:				

APPROVAL STATUS

<input type="checkbox"/>	Approved
<input type="checkbox"/>	Approved, but requires corrections of deficiencies and/or additional information prior to implementation.
<input checked="" type="checkbox"/>	Not Approved. 8.26.16

Reviewer: _____



Maurice L. Pantoja, Manager
Environmental Health

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PHARMACEUTICAL AND SHARPS PROGRAM - PLAN CORRECTION SHEET

QUARTERLY TAKE-BACK EVENT DAY PLAN

LOCATIONS, DATES AND TIMES

The plan contains the following information:

Met	Partial	Not met	Requirements	Reasons for Partial or Not Met
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dates of take-back event days ¹	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Locations of events serving the Unincorporated Communities ^{1,2}	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Hours of operation for each event ¹	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Commitment to reimburse County per event location for County participation at each quarterly take-back event ¹	
SECTION COMMENTS:			<p>UNABLE TO EVALUATE INSUFFICIENT INFORMATION PROVIDED</p> <p>It is our understanding that the Sheriff's Department has determined it will not accept your grant offer. Please submit an alternate detailed plan that addresses the requirements on this checklist. For example, contract with a pharmaceutical reverse distributor and sharps waste collector, such as Stericycle, to conduct such events.</p> <p>Commitment to reimburse the County per event location should cover costs by Sheriff's Department, Public Works, and Public Health.</p>	

REQUIREMENTS

The plan meets the following requirements:

Met	Partial	Not met	Requirements	Reasons for Partial or Not Met
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dates of take-back event days, cannot be in same month as DEA-sponsored take-back event days (October 2016) ¹	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Takeback events cover all five Supervisorial Districts (SD) and have been chosen from pre-approved County list provided to industry representatives ¹	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Minimum of ten unincorporated area communities per event day ¹	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Equivalent number of events in each SD (greatest extent feasible) ¹	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Date, location, hours and plan for each event will be submitted for approval by the Director at least 30 days in advance of each quarterly take-back event day ¹	
SECTION COMMENTS:			<p>UNABLE TO EVALUATE INSUFFICIENT INFORMATION PROVIDED</p>	

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QUARTERLY TAKE-BACK EVENT DAY PLAN

COLLECTION, TRANSPORT, AND DISPOSAL

Met	Partial	Not met	Requirements	Reasons for Partial or Not Met
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Safe collection of drugs/sharps at the event ¹	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Safe and approved transport of collected materials to disposal site ¹	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Safe and approved disposal of collected material ¹	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Permits or other required approvals needed for collection, transport and disposal of collected materials ¹	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Role and responsibilities of staff working the events, including name and cell phone number of a contact person for each location event ¹	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
SECTION COMMENTS:			UNABLE TO EVALUATE INSUFFICIENT INFORMATION PROVIDED	

APPROVAL STATUS

<input type="checkbox"/> Approved
<input type="checkbox"/> Approved, but requires corrections of deficiencies and/or additional information prior to implementation.
<input checked="" type="checkbox"/> Not Approved. 8.26.16

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 Environmental Health

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PHARMACEUTICAL AND SHARPS PROGRAM - PLAN CORRECTION SHEET

BENCHMARKS AND OUTCOME MEASUREMENT PLAN

EVALUATIONS AND REPORTS

The plan contains metrics to measure effectiveness of education and outreach to Unincorporated Communities (UCs), including the following requirements:

Met	Partial	Not met	Requirements	Reasons for <i>Partial</i> or <i>Not Met</i>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Quantities of each type of educational/outreach material disseminated in UC ³	Information provided was not specific to UCs
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Number of hits on campaign website, number of page views by residents of UCs ³	Information provided was not specific to UCs
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Report on survey responses from UC ³	Information provided was not specific to UCs
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Other measurements to determine if campaign raises awareness and changes consumer behaviors with respect to disposal in UC ²	Provide more details on the metrics for online and social media tracking
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
SECTION COMMENTS:			<ul style="list-style-type: none"> Education, outreach, and surveys should be targeted to UCs and reach a demographic range that minimally includes different ethnic and age groups. Recommend that a toll-free telephone number be established and promoted in the education and outreach plan, primarily providing information on the industry's take-back events. Metrics can be collected and provided regarding the utilization of this telephone number. 	

SURVEYS

Surveys in the UCs will meet the following requirements:

Met	Partial	Not met	Requirements	Reasons for <i>Partial</i> or <i>Not Met</i>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Be conducted before the launch of take-back events and the education and outreach campaign to create a baseline ¹	Information provided was not specific to UCs
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Be conducted after the launch of take-back events and the education and outreach campaign to measure outcomes and effectiveness ¹	Information provided was not specific to UCs
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Ensure the privacy of all respondents ¹	Plan does not state that it will ensure the privacy of all respondents
SECTION COMMENTS:			<ul style="list-style-type: none"> Surveys should be targeted to UCs Ensure that the sample size is statistically significant. Does the 500 surveys meet this criteria compared to a population of 1.2 million in the UCs? Survey respondents should be statistically relevant to UC population/demographics. Explain how will the 500 respondents be representative of a cross-section of the unincorporated area population. For example: Different ethnic groups (white, black, Hispanic, Asian) and age groups (seniors, adolescents, adults). Recommend providing surveys at take-back events in addition to the on-line surveys 	

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PHARMACEUTICAL AND SHARPS PROGRAM - PLAN CORRECTION SHEET

BENCHMARKS AND OUTCOME MEASUREMENT PLAN

SURVEY QUESTIONS

Survey questions will:

Met	Partial	Not met	Requirements	Reasons for <i>Partial</i> or <i>Not Met</i>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Assess the effectiveness of the education and outreach campaign on the use and proper disposal of drugs by UCs ¹	Not specific to UCs
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Be developed by an entity which has no personal ties to or financial interest to the outcome of the survey. Said entity must be a member of a neutral and reputable organization approved by the Director, including but not limited to the American Association for Public Opinion Research, the National Council on Public Polls, the Council of American Survey Research Organizations, or the Market Research Association ¹	The plan mentions only that survey will be developed by a "third party". Submit name of entity that meets listed requirements for Director approval.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Be in English, Spanish, and other languages as determined appropriate by Director of Public Health ¹	Survey questions need to be provided also in Spanish
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Be submitted for approval by Director of Public Health prior to dissemination to the public ¹	Plan does not state that survey questions will be provided for approval prior to dissemination
SECTION COMMENTS:			Survey questions should be designed to assess the effectiveness of the take-back program	

TIMELINES

The benchmarks and outcome measurement plan will:

Met	Partial	Not met	Requirements	Reasons for <i>Partial</i> or <i>Not Met</i>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Provide timelines for the start/implementation of each element of the plan (website traffic monitoring, material distribution, etc.)	Specific timelines not provided
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Require that survey results be submitted to Director of Public Health within 60 days of the end of the survey period established in the education and outreach plan ¹	Plan does not state that survey results will be provided to Director within the specific time period
SECTION COMMENTS:			Will metrics be evaluated only at end of Phase 1 or will there be mid-point reviews and adjustments?	

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BENCHMARKS AND OUTCOME MEASUREMENT PLAN

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<input type="checkbox"/>	Approved
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