January 9, 2015

Food and Drug Administration
Division of Dockets Management (HFA–305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

[Submitted electronically at www.regulations.gov]

Re: Development and Regulation of Abuse- Deterrent Formulations of Opioid Medications; Public Meeting and Request for Comments [Docket No. FDA–2014–N–1359]

Dear Sir/Madam:

The American Pharmacists Association (APhA) appreciates the opportunity to comment on the Food and Drug Administration’s (FDA’s) October 30-31, 2014 public meeting regarding the development, assessment, and regulation of Abuse-Deterrent Formulations (ADFs) of opioid medications. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

APhA would like to commend FDA for taking steps to incentivize and support the development, marketing, and research of ADFs and their willingness to interface with experts and stakeholders through advisory committees, industry guidances, and public meetings. Like FDA, APhA is concerned with promoting the appropriate use and the prevention of misuse and abuse of opioids and other prescription medications, and wants to be a strong partner in finding solutions to address this significant problem in the United States.

Generally, APhA supports the development, assessment, regulation, prescribing and dispensing of ADFs as an important component of a multipronged approach to addressing abuse of opioid medications. Opioid analgesics offer an effective solution for the treatment of pain and are often the treatment of choice for patients. APhA recognizes that because these medications are widely prescribed, the risk of misuse, abuse, addiction, overdose and mortality may be greater, and a transition to ADFs could contribute to the safe use of opioid containing products. As FDA takes steps to incentivize and support the development of opioid medications with progressively better abuse-deterrent properties, we ask the agency to balance the potential benefits to public health with the risks of creating barriers to valuable pain treatment options, such as increasing drug shortages and rising drug costs.
We thank the FDA for the opportunity to provide comments regarding ADFs. In the September 23, 2014 Federal Register notice announcing the public meeting and soliciting input, the FDA posed a number of questions to interested stakeholders. Below, we provide comments to those questions that touch on pharmacy practice.

I. Comment on the limitations of currently available abuse-deterrent technologies for solid oral dose forms of opioids and on the development of abuse-deterrent formulation technologies for non-solid oral dosage and the feasibility of requiring a class-wide reformulation approach

APhA is concerned that if substantially all opioid analgesics are manufactured with abuse-deterrent technology, then pharmacists may face challenges when titrating doses or compounding opioid preparations. In instances when a standard manufactured strength falls outside of the effective treatment range for patients, pharmacists routinely compound doses to suit the individual patients’ needs, such as for special populations (e.g., children, elderly, opioid-tolerant adults). As part of a standard compounding procedure, dosage forms may need to be changed--for example, tablets may need to be crushed in order to obtain the proper amount of drug needed to prepare doses. Tablets that are uncrushable or other challenging formulations such as liquids with mixed dose-dependent reversal agents could create access barriers for patients who need opioid analgesics tailored to their specific needs; therefore, it is impractical for FDA to require a class-wide ADF mandate.

II. Comment on FDA’s intention to approve language in NDA product labeling that accurately and fairly describes the abuse-deterrent properties of an opioid product if adequately supported by data

We believe that the accurate and fair labeling of any medication helps with the appropriate prescribing and dispensing of medication. However, according to a recent APhA survey of approximately 440 pharmacists, pharmacists and other health care providers also consider the out-of-pocket costs to the patient when recommending pain management regimens and making generic substitutions, thus labeling alone does not determine product selection.

III. Comment on FDA’s consideration of what circumstances the benefit/risk assessment methodology would support a refusal to approve, or withdrawal of approval for, an NDA for an opioid formulation lacking meaningful abuse-deterrent properties if an available therapy or therapies with meaningful abuse-deterrent properties exist

We believe that when assessing or reassessing the benefit/risk profile of an opioid product without abuse-deterrent properties, FDA should consider whether the number of available referenced listed drug (RLD) therapies on the market is sufficient. We urge FDA, when considering the refusal or withdrawal of non-ADFs based on the lack of abuse-deterrent properties and not due to other safety concerns, to consider the availability of other ADF products on the market so as not to affect patient access. The removal of opioid products from the market could cause drug shortages and barriers based on cost due to the lack of available products.
IV. Comment on special considerations associated with IR products that do not apply to ER/LA opioids

At present, there are a limited number of low-cost generic extended-release and long-acting (ER/LA) opioid options available for patients living with chronic pain. As a result, a large number of patients are on treatment regimens that consist of generic immediate-release (IR) opioid analgesics, prescribed as either a primary treatment option or as an adjunct therapy to suppress breakthrough pain. We remind FDA that policy changes that increase medication costs will affect a significant number of patients living with chronic pain.

V. Comment on FDA’s interest in encouraging the development and introduction of opioid products with progressively better abuse-deterrent properties, as well as the phase-out of products with less meaningful properties, as abuse-deterrent technologies improve

APhA is supportive of looking at ways to address the misuse and abuse of opioid products and believes the development of better abuse-deterrent products is an important component. However, APhA urges FDA to consider leaving non-ADFs of opioid analgesics on the market for use in patients and care settings where there is a less likelihood of abuse or diversion. Access to safe and cost-effective medications should be maintained for use in controlled care settings where there is limited patient/public access to the drug. Examples of these care settings include: hospitals, palliative care facilities, long-term care facilities, and ambulatory surgery centers.

Furthermore, once the market has adequate ADFs and non-ADFs of most RLD opioid analgesics, we urge FDA to work with state boards of medicine and pharmacy to assist them in developing guidance for practitioners regarding when it is appropriate to prescribe and dispense ADFs versus non-ADFs.

Conclusion

Thank you for considering our comments as FDA facilitates a market transition to ADFs of opioid analgesics. As FDA moves forward, we ask the agency to balance the perceived benefits to public health with the risks of creating barriers valuable pain treatment options. APhA thanks FDA for considering our feedback on this important public health initiative and we look forward to working closely with FDA and other stakeholders throughout the regulatory process. If you have any questions or require additional information, please contact Michael H. Ghobrial, PharmD, JD, Associate Director of Health Policy, at mghobrial@aphanet.org or (202) 558-2727.

Sincerely,

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Stacie Maass, BSPharm, JD, Senior Vice President, Pharmacy Practice and Government Affairs