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August 31, 2020

Lowell J. Schiller
Principal Associate Commissioner for Policy
Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Attention: FDA-2020-N-1069

Re: Approved Drug Products With Therapeutic Evaluations (the "Orange Book"); Establishment of a Public Docket; Request for Comments (FDA-2020-N-1069)

Dear Mr. Schiller:

The Academy of Managed Care Pharmacy (AMCP) thanks the Food and Drug Administration (FDA) for the opportunity to provide comments in response to its interim final rule with comment period titled "*Approved Drug Products With Therapeutic Evaluations (the "Orange Book"); Establishment of a Public Docket; Request for Comments (FDA-2020-N-1069)"* published on June 1, 2020. We appreciate the opportunity to leverage our members' expertise in offering feedback on this request.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, the Academy's 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

II. Establishment of a Public Docket and Request for Comments

- *Does the information regarding therapeutic equivalence promote drug competition? And if so, how?*

AMCP Response
Yes, the information regarding therapeutic equivalence does help promote drug competition. If a generic or other drug product is deemed therapeutically equivalent in the Orange Book, pharmacists can substitute these products for the reference product, thereby inducing competition between therapeutically equivalent products. In many cases, the generic drug is less expensive and as such, increasing competition between therapeutically equivalent drugs can lower costs for consumers and the health care system.

- *Is there any other information regarding the Orange Book that would be useful for FDA to consider?*

AMCP Response
The Orange Book would be more useful to pharmacists and managed care organizations if it included an indication as to whether a specific product is being manufactured, marketed, and/or distributed. For a listed active ingredient, the Orange Book may contain numerous approved products with multiple FDA approval dates, but it is unclear whether all of the listed products are available for use. Some companies may choose not to manufacture approved products and an indication, such as a designation marking products as "Available in the Market" or "Not Available in the Market," would make the Orange Book more useful for pharmacists and other stakeholders. Additionally, for the purposes of understanding whether a reference product exists, an indication that distinguishes between when a product is no longer on the market and when a product is withdrawn would improve the use and functionality of the Orange Book.

Furthermore, inclusion of a history of the product would be beneficial to stakeholders who use the Orange Book and FDA should consider including this information in product profiles.

Conclusion

AMCP appreciates the opportunity to comment on the Information Collection Request "*Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (CMS-1744-IFC).*" We are committed to being a valuable resource to CMS on improving access to prescription drugs at lower costs, reducing costs in the health care system, and improving access to pharmacy and telehealth services for Medicare beneficiaries. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell. RPh, CAE
Chief Executive Officer