Material Information (6446 PEC)					
SEQ_NO	1	Date of announcement	2025/09/22	Time of announcement	23:38:09
Subject	Announcement of the U.S. FDA’s Positive Preliminary Comments on the Filing for Expansion of Indication of BESREMi for Essential Thrombocythemia (ET)				
Date of events	2025/09/22	To which item it meets	paragraph 51		
Statement	1.Date of occurrence of the event:2025/09/22 2.Company name:PharmaEssentia Corp. 3.Relationship to the Company (please enter ”head office” or ”subsidiaries”): the company itself 4.Reciprocal shareholding ratios: N/A 5.Cause of occurrence: Regarding the planned submission of a new indication for BESREMi (ropeginterferon alfa-2b-njft) for essential thrombocythemia (ET) in the United States, PharmaEssentia had scheduled a Pre-sBLA meeting with the U.S. Food and Drug Administration (FDA) for September 23, 2025, to confirm submission details. However, on September 20, 2025, PharmaEssentia received the FDA’s Preliminary Meeting Comments, which provided clear and positive responses to all pre-submitted questions. In light of this, PharmaEssentia decided to cancel the Pre-sBLA meeting. Key Points from the FDA in the Preliminary Meeting Comments are as follows: (1)FDA agrees to use the global Phase 3 clinical trial SURPASS ET as the pivotal study and the North American Phase 2 clinical trial EXCEED-ET as the confirmatory evidence. The efficacy and safety data from these two clinical trials can serve as the basis for the BLA Efficacy Supplement of BESREMi for the treatment of adults with hydroxyurea-resistant or intolerant essential thrombocythemia. (2)FDA agrees that the content as outlined in the eCTD table of contents constitutes a complete Efficacy Supplement to support the proposed indication expansion. (3)FDA agrees to arrange an Applicant Orientation Meeting (AOM) after the submission of the application. (4)Regarding the final approved indication and the content of the Prescribing Information, as well as whether this case requires review by the Advisory Committee, the FDA stated that these decisions will be made during the review process. (5)Regarding whether this case qualifies for priority review, the FDA stated that the decision will be made upon the company’s submission 6.Countermeasures: PharmaEssentia will follow the FDA’s recommendations and promptly complete the compilation and submission of the sBLA of BESREMi for essential thrombocythemia (ET). 7.Any other matters that need to be specified (the information disclosure also meets the requirements of Article 7, subparagraph 9 of the Securities and Exchange Act Enforcement Rules, which brings forth a significant impact on shareholders rights or the price of the securities on public companies.): None				