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**Announcement:**Clarification of 02/02/11 Announcement Regarding Expedite and Informal Label and Formula Review Requests

On February 2, 2011, TTB announced a summary of improved electronic filing options for industry members, and some revisions to our standards regarding review and turnaround times for formula and certificate of label approvals. Given the significant increases in label and formula submissions, and the economic challenges that impact budgets throughout the Federal government, TTB continues to explore ways to become more effective and efficient in accomplishing our mission. In view of questions that have been raised concerning this announcement, we issue the following clarification.

## COLA Review Turnaround

In our [February 2nd announcement](#), we discontinued accepting "Expedite Requests" and "Informal Reviews" in order to allocate scarce resources for accurate processing of all Certificates of Label Approval (COLAs) and formulas on the basis of "first come-first served." As we pointed out, our regulations (see 27 CFR 13.21(b)) require us to notify applicants within 90 days of receipt whether we have approved or denied their applications. This regulation provides that TTB may extend this period for an additional 90 days where unusual circumstances require additional time to consider issues presented by the application. Until quite recently, we were able to act upon label applications within a shorter period. However, with a considerable increase in the number of applications TTB receives and shrinking resources available to TTB and the Federal government in general, we are, for the first time since 1999, facing serious challenges in our ability to maintain prompt processing times, which is one of our primary goals. To address the longer processing times that we predict, TTB is in the process of examining methods to continue the review and turnaround standards that we established as a matter of practice, within the parameters of existing law and regulations, and we are taking every step possible to make the reviews as accurately and as quickly as possible.

Expedited requests require more resources to process because TTB must spend time to determine whether each specific request meets the grounds for expedited treatment, rather than simply the time spent to evaluate and process the label application. While our regulations generally establish a 90-day timeframe within which TTB may process an application, you may be assured we will work hard to perform our review more quickly than that. However, we remind applicants that they should allow adequate time in planning for a label approval to account for the processing timeframe that the regulations provide, particularly since revisions to labels or formulas may be necessary and may cause delays that are not within TTB's control.

After TTB announced its policy on the discontinuance of expedited and informal reviews on February 2nd, we received several inquiries that, while expressing an understanding of the rationale underlying the policy, asked for a phase-in of the policy. Consequently, we wish to clarify that a phase-in policy is not necessary since requests that demonstrate good cause for expedited processing, such as requests presenting circumstances that are or were not reasonably within the applicant's control or ones which could not have been anticipated and planned for in advance through appropriate internal controls and procedures, may be processed in an accelerated manner. For purposes of fairness to the entire industry, and in order to address the backlog that TTB currently faces, we will consider this standard very narrowly. You may direct any written request (with full details on why good cause is present) for an expedited review to TTB's Advertising, Labeling and Formulation Division (ALFD) for evaluation. Informal label review, however, will not be conducted under any circumstances.

We encourage you to use all of TTB's available electronic applications, which include COLAs Online, Pay.gov, Formulas Online, and Permits Online. These venues streamline the processes involved, maximize public and industry resources, and allow TTB to better serve you.

Be on the lookout for TTB to continue a program of process improvements so we can better serve the interests of all parties. You may notice us making changes to our internal processes and improving them technologically in order to improve accuracy and timeliness. In all of these efforts, you have our continued commitment to provide the best possible service at the lowest possible costs to the taxpayers and to the industries we regulate.

We invite your comments on ways that we can improve both our processes and your interactive experience with TTB. Please direct all questions or comments to ALFD by calling 1-866-927-2533 or email us at [alfd@ttb.gov](mailto:alfd@ttb.gov).