（1）米国 FDA における GMP 策定作業が終了、制度化に向けて前進

待たれていた米国の健康食品 GMP は、FDA における作業が終了し、制度化の最終ステップに入りました。最終ステップの検討は Office of Manage and Budget (OMB)で行われ、問題があれば、通常 90 日以内に FDA に差し戻し、問題がなければ最終的な制度化となります。米国の業界筋では、OMB での作業は 2006 年の春までずれ込む可能性が高いとみているようですが、いずれにしても米国での健康食品ＧＭＰ制定化の最終段階に入ったことは確かなようです（IADSA「News flash　10 月号」より）。

英語版

（1）PUBLICATION OF DIETARY SUPPLEMENT GMPS IMMINENT?

Publication of the Food and Drug Administration's (FDA) final regulation on good manufacturing practices (GMPs) for dietary supplements moved a step closer to completion this week. The regulation was recently sent to the Office of Management and Budget (OMB) for review.

As part of the executive branch of government, the OMB conducts in-depth regulatory analyses and can be the last stop in the rule-making process.

The regulation, which is considered a "major" rule, could routinely take as long as 90 days to be reviewed.

Once OMB has reviewed the rule, it has the option of sending it back to FDA for additional changes.While the industry has remained hopeful that a regulation could be finalized by year-end, many experts are now predicting that the rule will not be finalized until early 2006.