



USAN First Policy

Per USAN Program policy, firms should apply for a non-proprietary drug name through their national nomenclature program first. In the United States of America, this national agency is the USAN Program.

In addition to being policy, there are benefits associated with applying for a USAN before an INN.

Benefits of Applying for a USAN First:

- 1) The name (proposed USAN) that will be reviewed by the INN Committee is cleared by the USAN Council (USANC) with review from the FDA. The FDA can refer to detailed information about the drug substance through the IND number on file. Because of this vetting, names submitted to the INN Programme by USAN carry more weight and are more likely to be accepted by the INN Experts. Typically, less than 10% of USAN sponsored names submitted to the INN will need re-discussion at a future USANC meeting.
- 2) As part of USAN services, USAN staff will file the INN application and submit additional materials on USAN applicants' behalf at no additional fee. (The INN application fee is \$12,000).
- 3) Less time is required to officially become an adopted USAN; USAN are adopted after the INN Expert meeting comment period expires and before the name appears in a published INN list.
- 4) Assistance from USAN staff in identifying the proper stem, suitable prefixes
- 5) Free USAN staff assistance is available throughout the USAN and INN application process.
- 6) Continuous balloting by the USANC occurs throughout the year. Unlike INN review, USANC review is not limited to biannual meetings.