

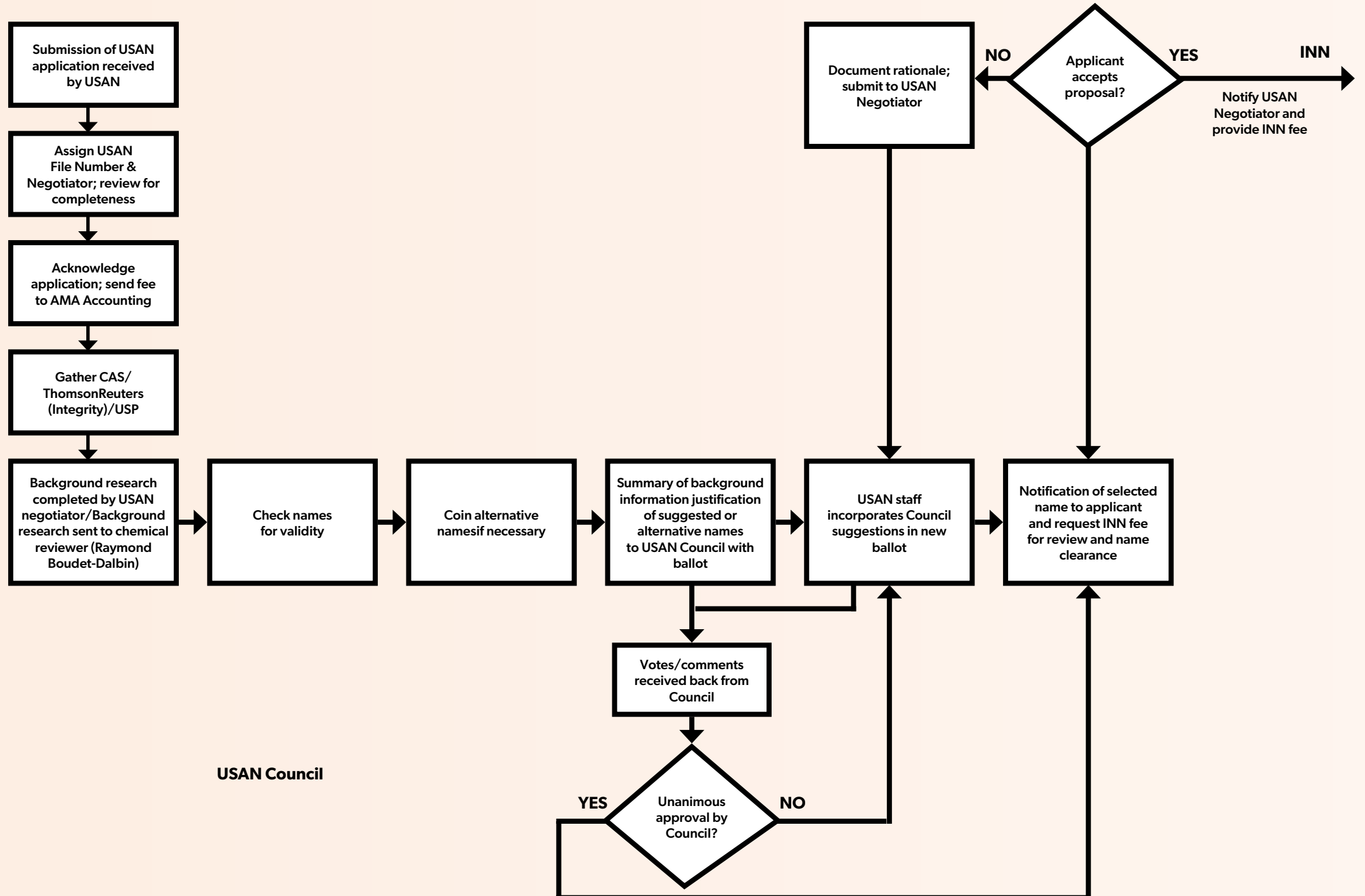
# USAN Negotiation Process

**Manufacturer**

**USAN Program Director**

**USAN Program Staff Assistant**

**USAN staff**  
(based on the negotiator)



# USAN Negotiation Process

## **Submission of USAN application received by USAN**

Drug manufacturer submits USAN application with payment to the [USAN Application portal](#).

## **Assign USAN File Number & Negotiator; review for completeness**

The USAN Director reviews application for completeness, assign a USAN file number, and delegate to the appropriate negotiator.

- Cell/Gene Therapy and small molecules – Stephanie Shubat
- MABs and small molecules – Gail Karet
- Contact Lens, USAN Modifications, and Revisions – Brad Wells

## **Acknowledge application; send fee to AMA Accounting**

USAN Staff Assistant (Miki Hewitt) sends letters to manufacturers acknowledging receipt of USAN application and payment via email. If a physical check is received we send to AMA accounting, or if payment was wired we notify AMA accounting and match payment with the assigned USAN file numbers.

## **Gather CAS/Thomson Reuters (Integrity)/USP - Background research completed by USAN negotiator/Background research sent to chemical reviewer (Raymond Boudet-Dalbin)-Check**

### **Names for Validity-Coin Alternative Names if Necessary**

The initial step taken by the negotiator is to review the chemical information including chemical name, structural and molecular formulas, and the molecular weight listed on the application. Check accuracy of CAS Registry Number supplied by looking CAS number up on <https://stnweb.cas.org/> . Check the proposed USAN names for conflicts with Thomson Reuters Integrity (<https://integrity.thomson-pharma.com/integrity>), USP Dictionary (<http://www.usp.org/products/usp-dictionary>), US National Library of Medicine National Institutes of Health – PubMed (<https://www.ncbi.nlm.nih.gov/pubmed/>), INN MedNet online (<https://mednet-communities.net/>), and trademark conflicts. The chemical information is then forwarded to USAN's chemical consultant Raymond Boudet-Dalbin who assigns or verifies the International Union of Pure and Applied Chemistry (IUPAC) name and review for accuracy the structural and molecular formulas listed by the manufacturer. If the negotiator finds that the proposed names are similar to existing USANs, then alternative names are coined by the negotiator at this time.



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## **Summary of Background Information Justification of Suggested or Alternative Names to USAN Council with Ballot; Votes/comments received back from Council; USAN staff incorporates Council suggestions in new ballot**

Once the chemical consultant's review is returned a ballot package is sent to the USAN Council. This packet includes USAN application, Chemical consultant review information, acknowledgement letter, USAN council ballot letter, Thomson Reuters Integrity information for mentioned compound, INN substance name research, and the USAN Council Ballot. Selecting a proposed adopted USAN requires a unanimous approval between the Council. Once the Council selects a proposed USAN the USAN staff negotiator is notified, then staff negotiator notifies the manufacturer of the Council's decision. If the Council is unable to agree on a proposed USAN the negotiator is notified to resubmit newly suggested names, and if appropriate, include any notes or suggestions from the USAN Council when coining suggested names.

## **Notification of selected name to applicant and request INN fee for review and name clearance**

Once a proposed adopted USAN is selected, the manufacturer will be notified and given the chance to accept or reject the Council's decision. Once the name is accepted and if applicable, the USAN negotiator then files INN application (including INN application fee) on behalf of manufacturer which includes appropriate background information to the WHO INN in Geneva, Switzerland via email and a FedEx hard copy. If the name is rejected, the negotiator documents the manufacturer's rationale and submits new names to the USAN Council to be voted on again. At this point the name proposed name is added to the "Names under Consideration" list (<https://www.ama-assn.org/about/usan-drug-names-under-consideration>) and the manufacturer should start the search to purchase a domain name.

## **Officially adopted as USAN/Publishing USAN**

Once the proposed USAN is accepted by the Council, the manufacturer, the INN Committee the name can be formally adopted as a USAN. The manufacturer is notified via adoption letter and adoption statement which is sent electronically by Mary Haynes. Upon receipt of this letter, the manufacturer has 60 day to review for accuracy, initial, and return to Brad Wells for publication. USAN adoptions are scheduled for the last Wednesday of each month. Within the 60 day review period, this is the time the manufacturer can make edits to the adoption statement without having to file a revised USAN application. When the 60 day review period is over Brad Wells publish the adopted USANs on AMA's website: <https://www.ama-assn.org/about-us/adoptednames>.

## **Helpful hint:**

***When the proposed name is acceptable to the USAN Council, the manufacturer, and the INN Expert Committee it then becomes an Adopted USAN.***



# USAN Negotiation Process

## Rules for Coining USAN Names: (<https://www.ama-assn.org/about/united-states-adopted-names-usan/united-states-adopted-names-naming-guidelines>)

1. Because of the international exchange of drug information, specific guidelines have been formulated to ensure appropriate translation of nonproprietary names into other languages. These rules of preferred phonetic spelling should be used:
  - The letter “f” should be used instead of “ph”
  - The letter “t” should be used instead of “th”
  - The letter “e” should be used instead of “ae” or “oe”
  - The letter “i” should be used instead of “y”
  - Avoid the letter “h”
  - Avoid the letter “k”
  - Avoid the letter “j”
  - Avoid the letter “w”
  - “ar,” “rac,” “lev,” “dex” or “es” are reserved for stereochemical configurations
2. Additionally, these letter combinations are restricted until further notice:
  - Avoid the beginning letter combination of “me”
  - Avoid the beginning letter combination of “str”
  - Avoid chemical connotations such as “ben,” “bu,” “cat,” “cel,” “fen,” “flu,” “fo(s)” and “piro,” unless chemically appropriate
  - Avoid chemical symbols unless present in the compound “al,” “ba,” “ca,” “li” and “ni”
  - Avoid “z” or “x” as a beginning letter
  - Avoid blends of 2 consecutive vowels
3. Individual letters, numbers or hyphenations are restricted to those groups of substances for which usage fulfills a clearly demonstrable purpose (e.g., interferon alfa-2b, pafluvocon A or technetium Tc 99m siboroxime).

