Response to Notice of Violation (RNOV)

- Defined in Section IV.H of the Ad/Promo Electronic Submissions Guidance
  - a correspondence type that includes a Firm's initial response to a warning letter or untitled letter (WL/UL)

  or

  - Additional correspondence pertaining to a warning letter or untitled letter
- An RNOV contains the following components
  - Correspondence stating that it is a response to a warning letter or untitled letter– either an initial or subsequent response
  - Corrective Pieces (if applicable)

Considerations

- RNOVs are subject to a response deadline
- OPDP recommends that a Sponsor's Publishing Team contact the OPDP RPM Team following receipt of a WL/UL
  - Contact OPDPeCTD@fda.hhs.gov
- OPDP RPM Team can provide overview of submission requirements
- eCTD provides the fastest option to submit a correspondence to the FDA
  - A correctly-coded eCTD submission can be processed and received by the OPDP Reviewer in as little as 15 minutes
- eCTD allows Sponsors to maximize the RNOV response period
  - No time lost to preparing and mailing response

eCTD – Best Practices

- Utilize test submission process
  - Allows Sponsors to submit a mock submission in the eCTD test environment
  - OPDP RPM Team will review the test submission and provide feedback
    - Test Submission Checklist available on the OPDP eCTD webpage
- OPDP Recommends that Sponsors submit a test RNOV in eCTD format
  - Document feedback and lessons learned from mock submission process and include in WL/UL Response Plan

Compliance Letter Web Posting Update

- Since 2018, OPDP Warning Letters have been posted in two locations
  - FDA Compliance Letter webpage
  - CDER Compliance Letter webpage
- Effective January 2021, OPDP Warning Letters will ***only*** be posted on the FDA Compliance Letter webpage
- OPDP Untitled Letters will continue to be posted on the CDER Compliance Letter webpage