

SmartSupplies LRA



SmartSupplies Label Routing and Approval

SmartSupplies LRA (Label Routing and Approval) is a fully web enabled software solution that will accelerate your label approval process in a manner that is compliant with industry standards, regional regulations and reduces costs. SmartSupplies LRA allows users to maintain and select pre-approved clinical phrases and translations and then route them for approval prior to printing.

Key Features and Benefits:

- Streamlines processes, increase employee efficiency eliminates the paper based process and reduces costs
- Provides a unified phrases and translations library that supports all international languages
- Easily tracks status and maintains a comprehensive history of the entire approval process
- Provides approval status for each phrase and translation
- Allows creation of reusable approval work groups
- Supports parallel, sequential or combination approval workflow processes
- Allows uploading of supporting documentation or diagrams throughout the system
- Optionally integrates with SmartSupplies LDP to insert approved phrases and translations onto label design canvases
- Ensures 21 CFR Part 11 compliance with full audit trail and reporting and electronic signature capabilities
- Group and user level security
- Provides email notifications to support the workflow of key process steps
- Supports LDAP authentication

Protocol: CLINOGEN_09023		Protocol: CLINOGEN_09023
Contains: Three bottles of CLINOGEN (clicnestrone) 400mg or placebo (70 tablets/bottle)	400mg or placebo	CLINOGEN (clicnestrone) 400mg or placebo Kit (3 bottles/kit)
Randomization No.: XXXX	Lot: XXXX	Randomization No.: XXXX
Date Assigned: ___/___/___	Subject No.: _____	Lot: XXXX
Instructions: Take one tablet by mouth twice daily with morning and evening meals.		Date Assigned: ___/___/___
Store at a controlled room temperature of 25°C (77°F); excursions permitted to 15-30°C (59-86°F). For oral use only. Keep out of reach and sight of children. Caution: New Drug—Limited by Federal (or United States) Law to investigational use.		Subject No.: _____
Sponsor: Clinapps Inc, San Diego, CA 92121		 

Phrases and Translations Library

A core component of the application is the library of clinical phrases and their language specific translations. Once approved, the phrases and translations can then be selected for use in one or more clinical label templates. The built-in document management component allows for certificates of translation to be uploaded with each translated phrase. A list of default phrases can be associated with each country to facilitate a rapid label development process and to ensure that country specific label text requirements are met.

Routing and Approval Process

Collaborative workflow processes are central to business success. The integrated work flow engine provides a configurable, electronic web based approval process for each label template or print request) Approvals can be configured for workgroups or individual workgroup members and supports both parallel, sequential or a combination approval processes. The electronic process provides proactive email notifications and allows users to Approve, Reject or Delegate the approval. A comprehensive history of all activity is maintained by the system and current routing/approval status is always visible to facilitate a streamlined label approval process and to provide the ability to view the routing progress. The flexible document management component allows for supporting documents, drawings or label proofs to be uploaded and made viewable to further reduce ambiguity and opportunity for error.

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