# SIRIUS

FDA-Listed Thermal Transfer Ribbons







Beginning in April 2006, the FDA is mandating the incorporation of bar codes on prescription drugs, certain over-the-counter drugs, container labels of blood and blood components intended for transfusion as well as other intravenous products. While not yet part of the FDA mandate, contract packagers of OTC drugs may also need FDA-approved labeling soon. Similarly, medical equipment manufacturers could benefit from implementing FDA-approved bar code labeling to track usage of their products.

The measure aims to prevent medication errors by adding accountability through more complete traceability – from the drug's origin through its administration, including the exact time, place and person dispensing it. As a result, the FDA believes it can help prevent nearly 500,000 adverse events and transfusion errors while saving \$93 billion in health costs over 20 years.





# Creating New Solutions for Today and Tomorrow

Drug delivery manufacturers are working closely with Dynic's development and testing labs to produce new solutions for a broad array of challenging applications. As an experienced and trusted U.S.-based TTR testing lab, we are uniquely positioned to develop special TTR formulations as well as to help match media to the best TTR products for unique medical applications.



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# Meeting the FDA Mandate

# **Keys to Success**

#### Quality

Label readability is an absolute necessity to ensure total accuracy and accountability.

#### **FDA Approval**

With pharmaceuticals, the label becomes an integral part of the package and the drug. Therefore, FDA approval of each component of the label – including the TTR – is a requirement for meeting the mandate.

#### **Fast Implementation**

With the April 2006 deadline looming, pharmaceutical and other affected companies will need to work quickly to implement FDA-approved solutions. Possible penalties for non-compliance include prosecution and potential legal liability from consumers.

#### Wide Range of TTR Solutions

Different applications require different solutions. Dynic offers a large variety of FDA-listed TTR products.

# **The Dynic Solution**

Dynic is the only major manufacturer that offers a full line of FDA-listed TTR products. Our solutions start with a proven record of quality and a family of products that delivers the best possible results and readability across a wide spectrum of applications. So regardless of your requirement, we have a pharmaceutical labeling solution that can fulfill your customers' needs.

Dynic distributors currently sell to most major pharmaceutical and drug manufacturers plus a host of medical device manufacturers. That's an advantage. Not only has it helped establish Dynic as a leading provider of FDA-listed TTR products, but it also helps minimize the time it takes to gain FDA approval for labeled pharmaceuticals affected by the FDA mandate.

### **Dynic FDA-Listed Products**

- S2 Stellar Wax
- L3 Wax-Resin
- S3 Wax-Resin
- HL21 Resin
- NK21 Resin
- HL30 Premium Resin

(also withstands autoclaving)

Drug master file numbers are available upon request for these products.

# **Dynic Food-Safe Ribbons**

- S2 Stellar Wax
- L3 Wax-Resin
- HL21 Resin
- A food-safe letter is available for these products.

- HL32 Harsh Environment Resin
- (also withstands autoclaving)
- HL35 Resin
- HL45 Alcohol Resistant Resin (IPA resistant withstands alcohol wipes in hospitals)
- HT8+ Near-Edge Wax-Resin
- HT8+ White Near-Edge Wax-Resin

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