



## Motrin Recall:

### Delay in Reporting Material Information

- 2 batches Motrin IB 200: 88,104 packages distributed in 8/08
- Dissolution problem identified in 11/08.  
Hold put on lots at Distribution Center
- FARs sent to FDA stated 3rd party contractor to perform “statistical sampling” of retailers to determine if recall necessary



## Motrin Recall (cont'd)

- FDA learned contractor was purchasing product found at retailer and employees were instructed to tell stores not to mention “recall”
- 7/09 McNeil initiated recall after contacted by FDA about 3<sup>rd</sup> party contractor activities
- Dissolution problem identified in 11/08; recall not initiated until 7/09