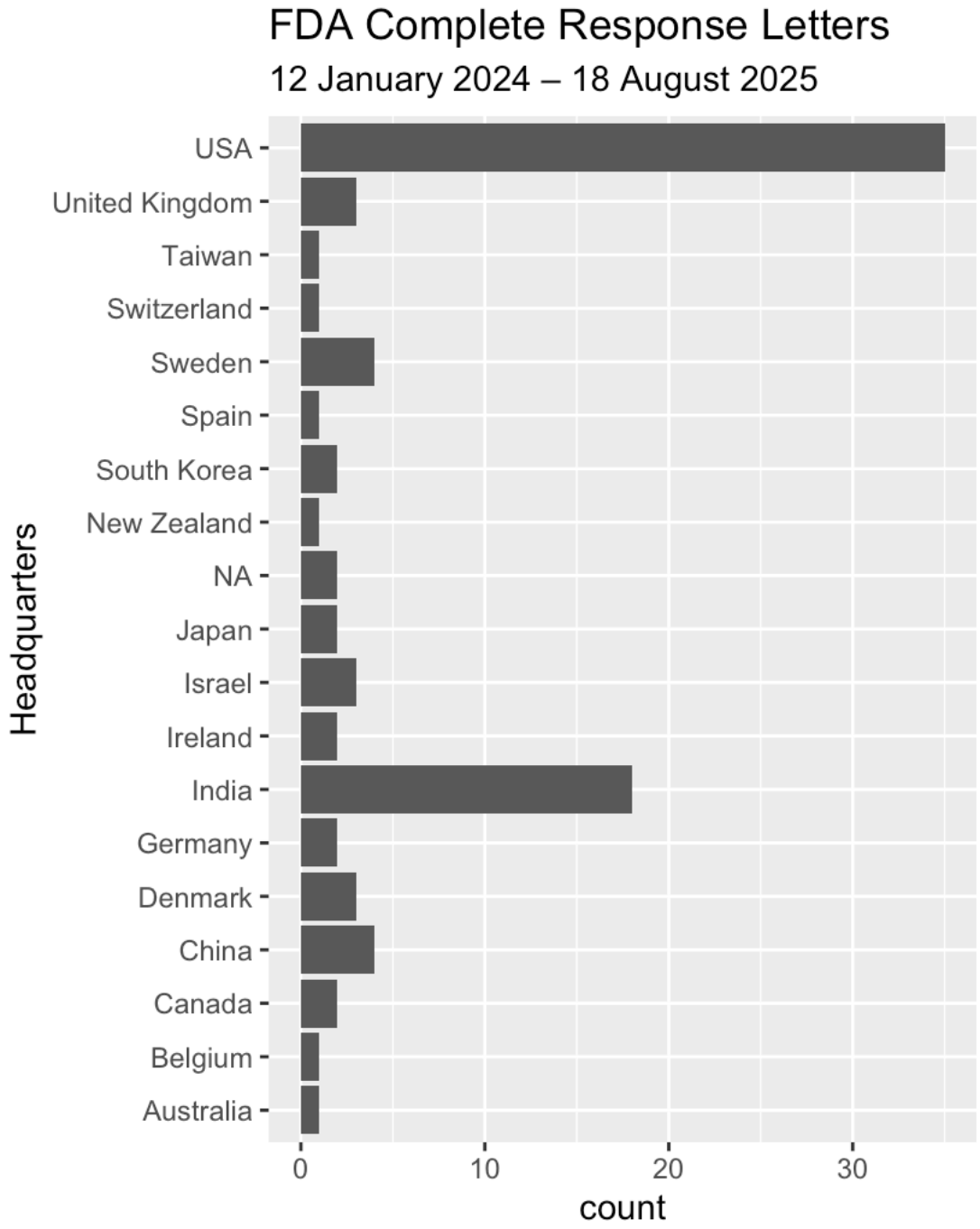
R code used for analysis of FDA Complete Response Letters

# Filename changed in R for easier handling
FDACRLs <- CRLs_NonAppr_FDARelease_04Sept2025

 # Plot: Location of applicant headquarters

```
ggplot(FDACRLs, aes(Headquarters)) + geom_bar() + coord_flip()+
labs(
    title = "FDA Complete Response Letters",
    subtitle = "12 January 2024 - 18 August 2025",
    x = "# Pages in Letter", y = "Count")
```



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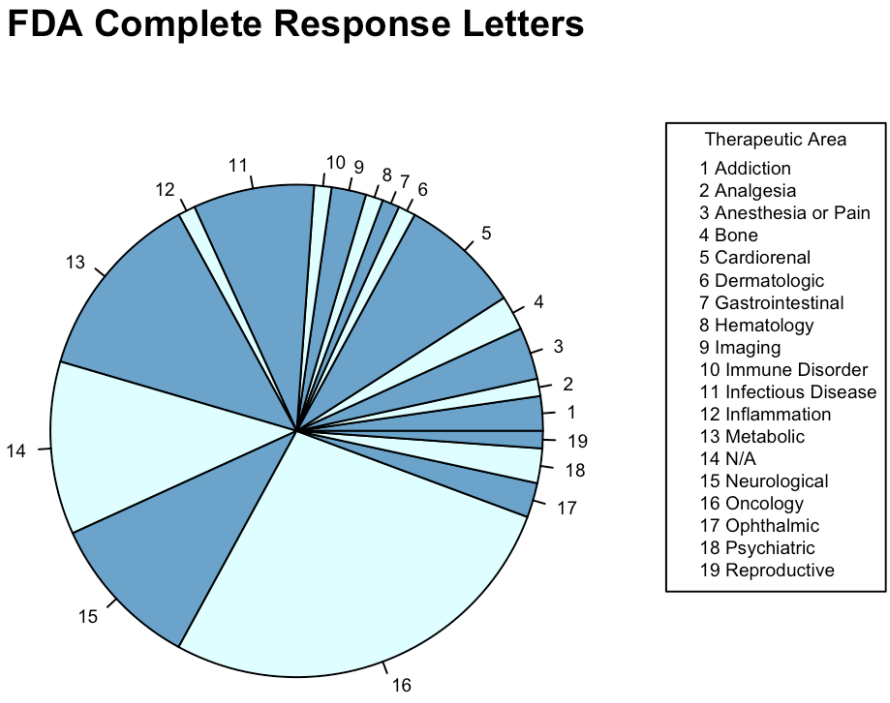
 # Plot: Therapeutic Areas represented in the letters

 # 1. Piechart

```
namepie <- names(table(FDACRLs$TherapeuticArea))
pie(table(FDACRLs$TherapeuticArea),
labels=1:length(namepie),
col = c("skyblue3","lightcyan1"), cex=0.6,
main = "FDA Complete Response Letters")

pieindex <- 1:length(namepie)
namepie <- paste(pieindex, namepie)
legend(x = 1.2, y = 1, namepie, cex = 0.6, title="Therapeutic
Area")
```



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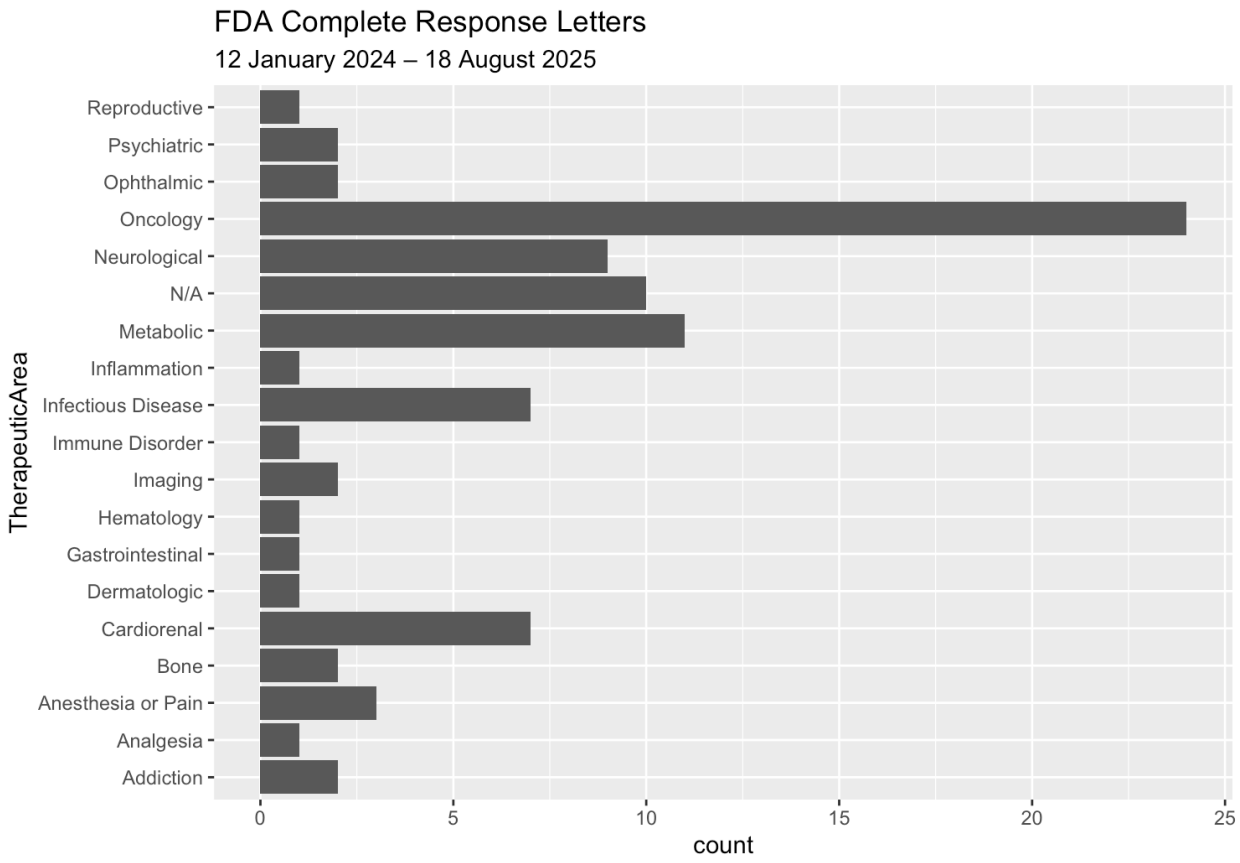
```
# 2. Barplot

ggplot(FDACRLs, aes(TherapeuticArea))+ geom_bar()+coord_flip()+
labs(
    title = "FDA Complete Response Letters",
    subtitle = "12 January 2024 - 18 August 2025")
```



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 # Plot: Issues in approval by discipline (Clin Pharm Earns an A-!)

```
IssueInApproval <- rbind(
     transform(table(FDACRLs$Regulatory)),
     transform(table(FDACRLs$ControlledSubstance)),
     transform(table(FDACRLs$Device)),
     transform(table(FDACRLs$HumanFactors)),
     transform(table(FDACRLs$Biopharm)),
     transform(table(FDACRLs$Statistics)),
     transform(table(FDACRLs$ClinicalPharmacology)),
     transform(table(FDACRLs$Nonclinical)),
     transform(table(FDACRLs$Clinical)),
     transform(table(FDACRLs$Quality)),
     transform(table(FDACRLs$Facility)))

IssueInApproval <- data.frame(
          Category = c(  rep("Regulatory", 2),
                         rep("ControlledSubstance", 2),
                         rep("Device", 2),
                         rep("HumanFactors", 2),
                         rep("Biopharm", 2),
                         rep("Statistics", 2),
                         rep("ClinicalPharmacology", 2),
                         rep("Nonclinical", 2),
                         rep("Clinical", 2),
                         rep("Quality", 2),
                         rep("Facility", 2)),
          ApprovalIssue = IssueInApproval[,1],
          Count = IssueInApproval[,2])

IssueInApproval$Category <- factor(IssueInApproval$Category,
levels = c("Regulatory", "ControlledSubstance", "Device",
          "HumanFactors", "Biopharm",
          "Statistics", "ClinicalPharmacology",
          "Nonclinical", "Clinical", "Quality", "Facility"))

ggplot(IssueInApproval, aes(x = Category, y = Count, fill =
ApprovalIssue)) +
     geom_bar(stat = "identity", position = "stack") +
coord_flip() +
scale_fill_manual(values=c('gray ', 'blue '))+
     labs(title = "Approvability Issue in Complete Response
Letter: 1/12/2024 - 8/18/2025",
          x = " ",
          y = "Count") +
theme(legend.position="none")
```

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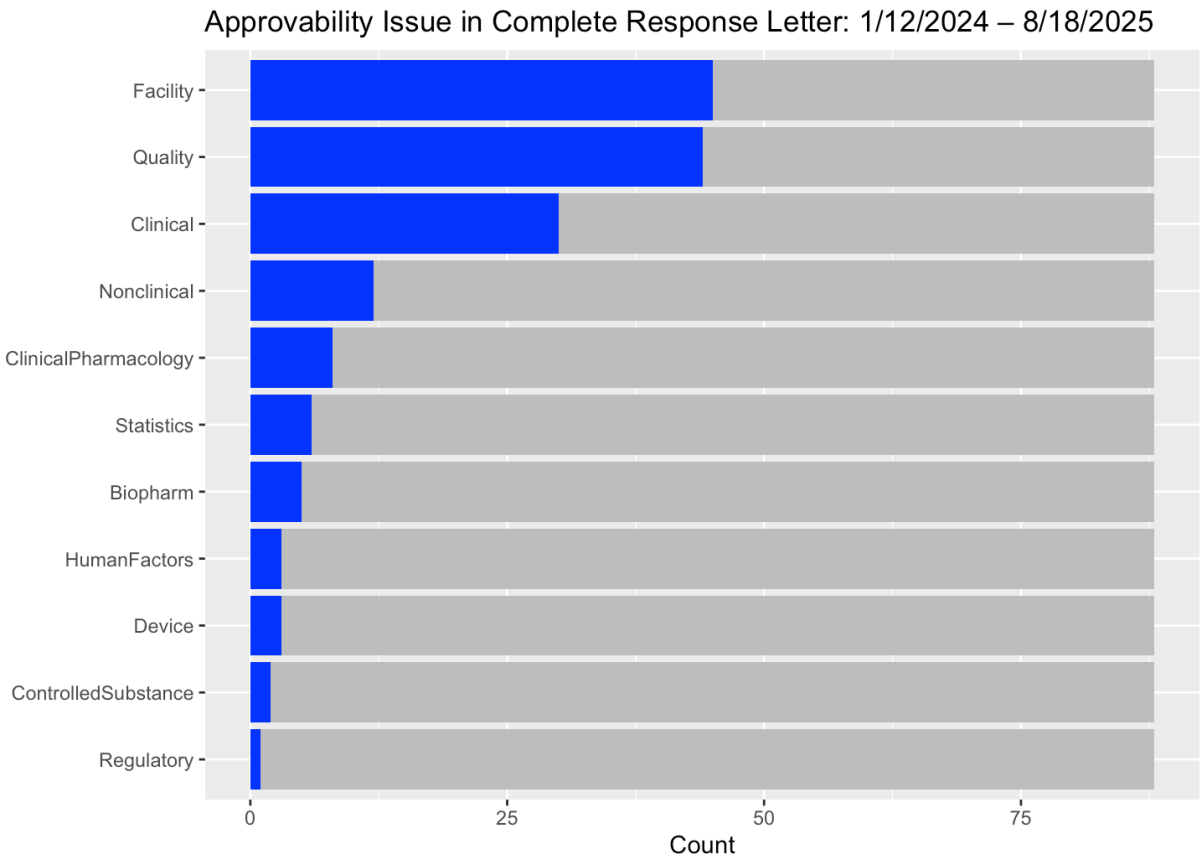

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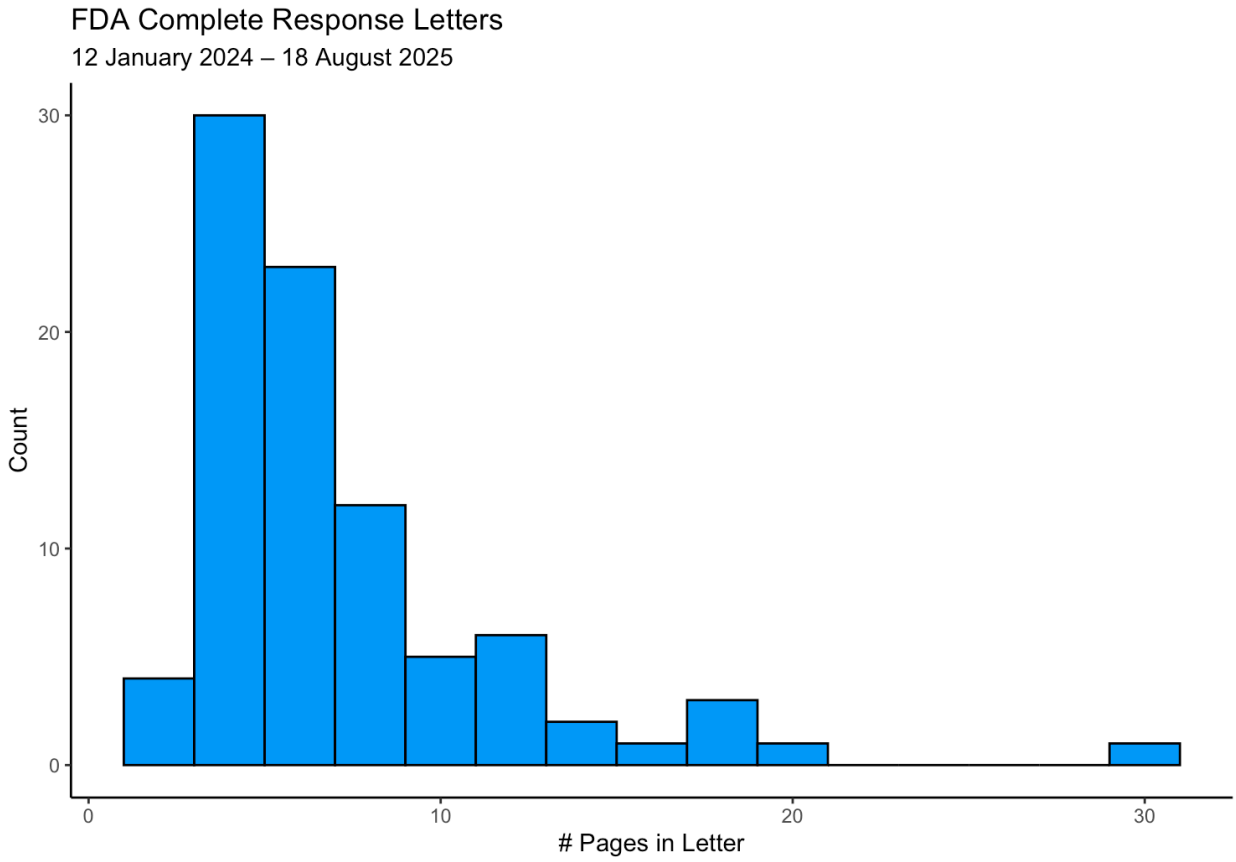
 # Plot: Number of pages in complete response letters

```
c <- ggplot(FDACRLs, aes(PagesInLetter))
# c + geom_histogram(binwidth = 2, fill="steelblue", ) +
c + geom_histogram(binwidth = 2, color = "#000000", fill =
"#0099F8") +
labs(
    title = "FDA Complete Response Letters",
    subtitle = "12 January 2024 - 18 August 2025",
    x = "# Pages in Letter", y = "Count") +
     theme_classic()
```



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